ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 704 and 799

[OPPTS-42038A; FRL 3883-4]

RIN: 2070-Ab07

Aryl Phosphate Base Stocks; Proposed Test Rule Including Reporting and Recordkeeping Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes that manufacturers, importers and processors of chemical substances in the category of aryl phosphate base stocks be required, under section 4 of the Toxic Substances Control Act (TSCA), to conduct testing. For this Proposed Rule, aryl phosphate base stocks are phosphate esters or combination of esters resulting from the reaction of a phenol, mixtures of phenols, or a combination of alkyl-substituted phenols or, in some cases, phenols plus an alcohol, with phosphorus oxychloride ($POCl_3$) or other phosphoric acid derivatives. This definition includes triaryl and mixed aryl/alkyl esters (where one or two of the three ester groups are alkyl). Base stocks are initially manufactured aryl phosphates from which other aryl phosphate products are produced, and are often commercially available. The proposed testing includes chemical analysis and, at certain production volumes, chemical fate and health and environmental effects. This is a category rule to which every substance fitting the above definition would be subject. EPA is also proposing, under TSCA section 8(a), that manufacturers and importers of aryl phosphate base stocks be required to report to EPA the volume of substances manufactured and imported, in accordance with 40 CFR part 704, to allow EPA to determine when certain tests are to be performed. This rule is being proposed under the authority of TSCA sections 4(a)(1)(A) and (B), 8(a), and 26(c)(2). This rule requires that testing be conducted to develop data with respect to health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substances or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

DATES: Submit written comments on or before April 16, 1992. If persons request an opportunity to submit oral comments by April 1, 1992, EPA will hold a public meeting on this proposed rule in Washington, DC. For information on arranging to speak at the meeting, see Unit VII of this preamble.

ADDRESSES: Submit written comments, identified by the document control number OPPTS-42038A, in triplicate, to: TSCA Public Docket Office (TS-793), rm. NE-G004, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. A public version of the administrative record supporting this action (with confidential business information deleted) is available for inspection at the above address from 8 a.m. to 12 noon, and 1 p.m. to 4 p.m. Monday through Friday except legal holidays.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: Under section 4(a) of TSCA, EPA shall, by rule, require testing of a chemical substance or mixture (substance) to develop health or environmental data if the Administrator makes certain findings described in TSCA under section 4(a)(1)(A) or (B). Detailed discussion of the TSCA section 4 findings are provided in EPA's first and second proposed test rules, which were published in the **Federal Registers** of July 18, 1980 (45 FR 48524) and June 5, 1981 (46 FR 30300). The aryl phosphate category proposed for chemical analysis, chemical fate, environmental effects and health effects testing includes any chemical fitting the category definition in this proposal that is listed now or in the future in public or confidential portions of the TSCA section 8(b) Inventory of Chemical Substances.

EPA is also proposing, under TSCA section 8(a), that manufacturers and importers of these substances report annual production and/or importation volumes. This information will be used by EPA to trigger testing at levels predetermined by EPA.

The aryl phosphates are a complicated category of chemicals that present unique factors to consider in developing an appropriate test rule. EPA expects to seriously weigh all alternative approaches and may promulgate a test rule that is substantially different from today's proposal.

I. Introduction

This rule requires manufacturers of aryl phosphate base stocks to analyze them chemically and test them for chemical fate, environmental and health effects. The testing requirements are divided into two stages. Stage one is to determine the chemical identity of the base stocks being produced during the period this rule is in effect. Stage one testing requires chemical analysis of base stocks by gas chromatography/mass spectrometry (GC/MS). All manufacturers of aryl phosphate base stocks must perform stage one testing on each base stock they manufacture and report the results to EPA. Since these analytical data may be unique to each manufacturer's product they can not be jointly developed. EPA will use these data to determine equivalency of test substances for stage two testing. Manufacturers of base stocks EPA judges to be equivalent may jointly sponsor stage two testing.

Stage two testing is to determine the chemical fate, environmental effects and health effects of aryl phosphates. To minimize the economic impact of the rule, stage two testing is divided into three levels based upon the annual production volume of the base stock. Aryl phosphate base stocks produced at or above 1 million pounds per year are subject to level one testing requirements. Level one consists of 120-day post-hatch rainbow trout early life stage testing (ELS), three hen

neurotoxicity assays, and a two-generation reproductive effects study. Level two testing is triggered by a production volume of 5 million pounds or higher. It includes anaerobic biodegradation, chronic Daphnia, and subchronic toxicity testing. Aryl phosphate base stocks produced at or above 10 million pounds would be subject to level three testing. Level three includes aerobic biodegradation, microcosm effects, developmental toxicity, and the subchronic rat neurotoxicity battery.

To determine if base stocks have met the trigger levels, EPA is proposing a section 8(a) reporting requirement. EPA would notify manufacturers when the production triggers were met.

A. Definitions

"aryl phosphate" for this proposed rule is a phosphate triester of phenol or of an alkyl-substituted phenol. This definition includes triaryl and mixed aryl alkyl esters (where one or two of the three ester groups are alkyl), and can denote structurally unique substances, base stocks, or downstream products.

"Aryl phosphate base stock" means the phosphate ester or combination of esters resulting from the reaction of a phenol, mixtures of phenols, or, in some cases, phenols plus an alcohol, with phosphorus oxychloride ($POCl_3$) or other phosphoric acid derivatives (see Unit I.C.1 of this preamble for a fuller discussion). This definition includes triaryl and mixed aryl/alkyl esters (where one or two of the three ester groups are alkyl). This reaction can produce a near-pure triaryl phosphate such as triphenyl phosphate (when phenol is used), a mix of aryl phosphates (as when a mix of an alkylphenol and phenol is used) or a mix of isomeric esters such as ortho-, meta- and paracresyl phosphates. Mono and dicresyl esters would also be possible reaction products in the latter example. Base stocks are initially manufactured aryl phosphates from which other aryl phosphate products are produced and are often commercially available. The base stock components remain unreacted in these aryl phosphate products. Thus, when an aryl phosphate product is released into the environment, the base stock components in the product are released into the environment. Likewise, when humans are exposed to aryl phosphate products, they are exposed to the base stock components that are in the products.

"Chemical" means any organic or inorganic substance of a particular molecular identity.

"Complex substance" means a "chemical substance" as defined under section 3 of TSCA that is composed of related chemicals produced as "*** a result of a chemical reaction." Most aryl phosphate base stocks, as defined in this proposal, are complex substances. The names of these substances generally refer to the major component.

"Component" and "constituent" are used interchangeably, and mean one of the individually identified chemicals that, together with other components, comprise a complex substance.

"Feedstocks" are alcohols or phenols used in the manufacture of aryl phosphate base stocks. They may be single or mixed alcohols.

"Isomer" means one of two or more chemical compounds containing the same numbers of atoms of the same elements, but differing in structural arrangement. For example, tri-orthocresyl phosphate (TOCP), with its methyl substituent at the ortho position of the phenyl group, is one of three pure tricresyl phosphate isomers (the others being the tri-meta and tri-para isomers).

"Mixture" is defined in TSCA section 3(8). In the case of aryl phosphate products, a mixture includes combinations of two or more aryl phosphate base stocks, or of an aryl phosphate base stock and other chemicals, but does not include those defined in this proposed rule as "complex substances".

"Product" means the final commercially manufactured substance. It may be a single base stock, a mixture of different base stocks or a mixture of a base stock with an unrelated substance. The product Phosflex 370, for example, is a mixture of the base stocks isodecyl diphenyl phosphate and *tert*-butylphenyl diphenyl phosphate.

"Substituent" means an atom or group that replaces another atom or group in a molecule. In xylol (dimethylphenol), two hydrogens of the phenyl moiety are replaced by two methyl substituents.

B. Background

1. *ITC designation.* The Interagency Testing Committee (ITC) designated the aryl phosphate category for priority testing consideration in its second report. The reasons for this designation are discussed in the **Federal Register** of April 19, 1978 (43 FR 16684).

The ITC defined the category as "***phosphate esters of phenol or of alkyl-substituted phenols. Tri-aryl and mixed alkyl and aryl esters are included, but tri-alkyl esters are excluded." The ITC recommended testing for "carcinogenicity, mutagenicity, teratogenicity, other chronic effects, environmental effects and epidemiology."

2. *Advance Notice of Proposed Rulemaking (ANPR)*—a. *Summary.* The Agency published an ANPR on aryl phosphates on December 29, 1983 (48 FR 57452), following discussions with the Industry Ad Hoc Aryl Phosphate Ester Committee (IAPEC). The ANPR proposed testing nine aryl phosphate complex substances because they had been "identified by industry as being constituents of commercial products currently in production."

The nine substances proposed for testing in the ANPR were: (1) Tricresyl phosphate (TCP), mixed isomers (tritolyl phosphate, CAS Nos. 1330-78-5 and 68952-35-2); (2) Trixylenyl phosphate (TXP), mixed isomers (trixylyl phosphate, CAS Nos. 25155-23-1 and 68952-33-0); (3) Triphenyl phosphate (TPP) (CAS No. 115-86-6); (4) Nonylphenyl diphenyl phosphate (NDP), mixed isomers (CAS No. 38638-05-0); (5) Dimethylbenzylphenyl diphenyl phosphate, mixed isomers (CAS No. 34364-42-6); (6) Isopropylphenyl diphenyl phosphate (IPP), mixed isomers (CAS No. 28108-99-8); (7) *tert*-Butylphenyl diphenyl phosphate (BDP), mixed isomers (CAS No. 56803-37-3); (8) Isodecyl diphenyl phosphate (IDP) (CAS No. 59800-46-3); (9) 2-Ethylhexyl diphenyl phosphate (EDP) (CAS No. 1241-94-7). All were base stocks as defined in this proposed rule.

The ITC designated these chemicals because they were "*** produced in [aggregate] quantities exceeding 65 million pounds/year," NIOSH had estimated exposure of over 2 million workers, and certain members of this chemical class had known toxicities.

Testing proposed for aryl phosphates in the ANPR included: chronic effects - 90-day subchronics; mutagenicity--all substances for some aspect of mutagenicity; oncogenicity (triggered by mutagenicity or data from the 90-day subchronics); teratogenicity for TCP, and for TXP, IPP, BDP, IDP, and EDP if triggered by TCP; reproductive effects for TCP and others if triggered by TCP results; 90-day subchronic neurotoxicity for TCP and TXP; environmental effects — field monitoring studies, tissue residue analyses of biota exposed to water and sediment collected from sites known to contain aryl phosphates at measurable levels and testing on terrestrial organisms. Epidemiology studies were not considered for proposal in the ANPR.

b. *Comments.* EPA requested comments on eight issues in the ANPR, and received comments from eight sources: IAPEC, five corporations (Ciba-

Geigy, Eastman Kodak, FMC, Monsanto, Stauffer), the Environmental Defense Fund (EDF), and D. Muir of the Canadian Fisheries and Wildlife Service. Summaries of the issues and comments submitted and the Agency's response to each appear below.

1. *Issue.* EPA requested information on persons exposed to aryl phosphates from synthetic feedstocks, the type of exposure, notable changes in production of individual substances over the last 5 years, new applications planned for any of these substances and projected growth rate over the next 5 years.

Comments. The IAPEC commented that aryl phosphate production reflects a "mature product category and market growth rate is projected below GNP levels." It stated that production declined between 1979 and 1982, and that EPA should use this production decline when predicting the future trend. IAPEC estimated that fewer than 200 workers are involved in production. It was also exploring a "user survey to address possible concerns" (the Agency has not received any such survey to date). Eastman Kodak Company and FMC also commented about the reduced production. Kodak commented on the lack of justification for a 4(a)(1)(B) finding. Stauffer Chemical Company commented that fewer than 90 of its employees are exposed to aryl phosphates and that downstream worker exposure is insignificant. Stauffer also estimated exposure levels of less than 1.0 part per billion (ppb) to air-borne aryl phosphates during each working day. Stauffer estimated that dermal exposure occurs during less than 20 percent of the day, and that this is minimized by protective clothing worn by its employees. Stauffer also commented that low vapor pressure (typically <0.1 mm Hg at 100 °F) of listed aryl phosphates reduces the potential for inhalation exposure to an insignificant level under typical operating conditions.

EPA Response. The ANPR gave levels of projected production in 1980 as 100 to 140 million pounds. Manufacturers subsequently submitted production levels of individual substances to EPA as confidential business information (CBI). However, EPA's current estimate of aggregate category production, 72.1 million pounds, is available (Ref. 6).

A 1986 EPA report provided information indicating that, although the production levels of individual aryl phosphates dipped to an all-time low in 1982, they subsequently grew 10 percent or more by 1984 (Ref. 38). Information in the Partial Inventory Update Rule (Chemical Update System, CUS) (Ref. 69) shows that, in 1986, levels were down from the highs mentioned in the ITC report, but not to the extent that manufacturers were predicting. According to EPA's assessment, production of this category remains substantial. There has, however, been a reduction in production of some individual base stocks listed in this proposed rule.

IAPEC commented that only about 200 workers are exposed. However, this reference was to manufacturing workers only. Many more workers are exposed while using the end product(s). The 1980 National Occupational Hazard Survey (NOHS) update shows more than 2 million workers may be exposed to aryl phosphates (Ref. 51). It is difficult to evaluate exposure numbers in subsequent data, e.g., the National Occupational Exposure Survey (NOES) (Ref. 52), because of inconsistent reporting terminology.

For purposes of reporting to the TSCA section 8(b) Chemical Inventory, EPA allows manufacturers of a complex substance to report it as such or as its individual components. This makes it difficult to ensure acquisition of all the information relating to the complex substance. For example, NOES (Ref. 52) shows 69 workers exposed to IPP (CAS No. 28108–99–8), one of the substances listed in the ANPR. However, NOES also shows 46,946 workers exposed to "isopropylated phenol, phosphate (3:1)" (Cas No. 68937–41–7), a complex substance that may contain varying amounts of isopropylphenyl diphenyl phosphate (IPP), bis(isopropylphenyl) phenyl phosphate, and/or tris(isopropylphenyl) phosphate, depending upon the degree of propylation required for the desired end properties.

Exposure in the workplace occurs via dermal contact and inhalation. EPA estimates inhalation exposure of TPP may be as high as 150 mg/day (Ref. 35). The 1986–1987 issue of the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values reference book (Ref. 3) listed two aryl phosphates, TPP and TOCP. ACGIH recommends a time-weighted average (TWA) threshold limit value (TLV) of 3 mg/m^3 (cubic meters) for TPP in air, and a TWA TLV of 0.1 mg/m^3 for skin contact with TOCP. Most aryl phosphate base stocks are liquids with high boiling points, but they may be volatile or form an aerosol in certain applications. For example, a NIOSH walkthrough of a General Motors Die Cast Department in Rochester, NY, in which aryl phosphate-containing hydraulic fluids were used at 100 °F, found TPP and IPP in the air at 0.57 and 0.013 milligram (mg)/cubic meter (m^3), respectively (Ref. 75).

Aircraft maintenance workers may have frequent dermal contact with hydraulic fluids containing aryl phosphate base stocks. EPA estimates such exposure to be in the 1300 to 3900 mg/day range if no protective clothing is worn (Ref. 35). EPA described this exposure pattern in its proposed test rule for tributyl phosphate (TBP) (Ref. 71). EPA believes exposure level estimates for users of aircraft hydraulic fluids containing TBP are applicable to users of those containing aryl phosphate base stocks.

2. *Issue.* Would analytical data from the manufacturers of commercial TCP showing the TOCP level of their commercial product, when combined with the results of EPA's proposed 90–day subchronic neurotoxicity study using three dose levels of TOCP, enable the Agency to reasonably determine or predict the neurotoxicity of a TCP commercial product?

Comments. EDF recommended subchronic testing of TOCP and the TCP mixture, while IAPEC and Stauffer mentioned the difficulty and expense of testing pure isomers and suggested testing products instead. Stauffer discussed the use of acute toxicity and percent ortho-cresol as an acceptable neurotoxicity approximation rather than the subchronic test. Stauffer also mentioned a 7–dose-level TOCP toxicity study published in conjunction with the Delayed Neurotoxicity Workshop it recently co-sponsored.

EPA Response. EPA is not proposing toxicity testing of pure TOCP at this time, but is proposing the produced base stock which may or may not include TOCP. EPA did consider the multi-dose study of TOCP (Ref. 56 and 57); however, published data on the test substance and methodology do not give enough information for EPA assessment.

The ANPR also stated that a 90–day subchronic test of TOCP, then under way as a positive control to FMC's 90–day study of IPP, was not an appropriate neurotoxicity test for TCP because it was only a single-dose study. The testing scheme discussed in the ANPR would have required a full 3-dose study of TOCP. The FMC TOCP study received in 1986, although a 2-dose study, was therefore still unacceptable (Ref. 24).

Studies performed on individual tricresyl phosphate isomers indicated the major neurotoxicant was TOCP (Ref. 63). Manufacturers, therefore, endeavored to reduce the TOCP content of their products. However, a recent TSCA section 8(e) submission (Ref. 40) indicates TOCP-reduced (less than 0.1 percent) products have neurotoxic

effects on the hen similar to those arising from exposure to pure TOCP.

EPA believes aryl phosphate testing should focus, at this time, on the complex substances to which people may be exposed. This proposed rule would require testing of base stocks, but not individual chemical constituents or product mixtures (see Unit I.C.3 of this preamble for fuller discussion of test substances). Thus, for isopropylated phenyl phosphates, three base stocks are proposed for testing: isopropylphenyl diphenyl-, bis(isopropylphenyl) phenyl-, and tris(isopropylphenyl) phosphate. Each of these base stocks contains smaller but significant amounts of one or both of the other isopropylated phenyl phosphates. EPA would use test data obtained on base stocks to help determine whether or not testing individual constituents would be necessary.

3. *Issue.* Does the potential for human exposure to certain consumer products containing acutely neurotoxic TXP components warrant subchronic neurotoxicity testing?

Comments. EDF commented that all organophosphates should be tested for subchronic neurotoxicity, not just those selected on the basis of acute data. It specifically suggested testing of IPP and TXP. IAPEC stated that "the neurotoxicity of TXP has been determined," and that "*** human exposure is insignificant. As commercial production continues to decline, no further testing is warranted." Stauffer commented that subchronic testing would be appropriate if exposure were significant, but in any case, an acute test should be performed to determine if subchronic testing is necessary.

EPA Response. EPA believes that acute organophosphorus induced delayed neuropathy (OPIDN) testing combined with acute neurotoxic esterase testing is a valid predictor for the OPIDN syndrome. The subchronic testing is primarily for risk assessment purposes.

EPA does not believe the neurotoxicity of TXP has been adequately determined, and is proposing testing of this complex substance in this test rule. In the case of IPP, the ANPR did not discuss possible subchronic neurotoxicity testing because, at the time, FMC was planning a 90-day subchronic assay of IPP in the hen that was expected to reasonably predict or determine IPP neurotoxicity. However, the data FMC submitted to EPA characterizing the composition of the test material was insufficient for evaluation of the study (see Unit II.C.2 of this preamble).

4. *Issue.* Is TOCP the only agent responsible for the suggested reproductive and teratogenic effects of TCP? Should it be tested separately? Do the existing data for TOCP provide sufficient evidence to implicate other aryl phosphates?

Comments. EDF said all aryl phosphates should be tested. The IAPEC took the position that because no scientific data indicate TOCP or tricresyl phosphates have reproductive or developmental effects, there is no justification for further testing. It stated that because five important commercial aryl phosphates were negative in teratogenicity studies, there was no need for further testing. Stauffer stated that the information on TOCP did not justify any type of reproductive or developmental toxicity testing. The company asserted that validity of seminiferous tubule degeneration observed in a study of male rabbits and dogs with TCP (Ref. 14) must be questioned. Without knowing what was tested, it is difficult to draw any meaningful conclusions. Finally, Stauffer stated testing TOCP had no relevance to predicting the effect of exposure to compounds in commercial production.

EPA Response. EPA is not proposing testing of any component, including TOCP, of any of the complex substances in this test rule. EPA agrees with Stauffer that testing single components of an aryl phosphate is not appropriate at this time, and instead proposes testing of actual manufactured aryl phosphate base stocks (see Unit I.C.3 of this preamble).

The data IAPEC referred to included minimal chemical analysis on the products tested and is of limited use for assessment of hazard potential.

Three recent studies have demonstrated the reproductive toxicity of TCP in several species and strains of laboratory animals (Refs. 12, 13, and 15). The National Toxicology Program (NTP) and National Institute of Environmental Health Sciences (NIEHS) studies both used TCP with less than 0.1 percent TOCP, while the TCP in the EPA study contained less than 9 percent TOCP. All three studies showed effects on male reproductive parameters, and histopathologic effects were seen in the ovaries in the EPA-sponsored study. Both the EPA-sponsored and NIEHS-sponsored studies demonstrated developmental toxicity, while the NIEHS study also showed effects in the F_1 generation at the lowest dose. A confidential TSCA section 8(e) study was submitted to EPA in 1990 demonstrating similar reproductive effects with an additional aryl phosphate.

5. *Issue.* Is it possible to reduce the testing burden by forming subcategories of similar aryl phosphates or by testing a subset that spans the structural spectrum of the aryl phosphates category?

Comments. EDF stated that information about possible toxicity of these compounds was insufficient to justify such approaches. Kodak suggested a decision to choose subcategories should be based on quantities being manufactured and potential exposure, and it would be inappropriate for EPA to decide this matter until these data were available. IAPEC stated that structural subsets could be developed if a need for further testing was demonstrated, and added there was no need to conduct separate tests for each chemical.

EPA Response. EPA has decided not to pursue these possibilities for aryl phosphates at this time. The use of subcategories or subsets for testing implies that the results of such surrogate testing would be valid for all the chemicals not tested. EPA is not convinced there is a sufficient understanding at this time of the relationship of structure and observed toxicity to subcategorize aryl phosphate base stocks for testing.

6. *Issue.* EPA sought comments on criteria used to evaluate the industry-sponsored monitoring study. These included: (i) Detection limit sensitivity; (ii) quality assurance evaluation; (iii) location and selection of sampling sites; (iv) statistical treatment of data obtained; (v) analytical method; and (vi) interpretation of results.

Comments. IAPEC commented on the six criteria as follows:

a. *Detection limit sensitivity.* IAPEC contends the monitoring study they submitted demonstrates adequate margins of safety, and while recoveries were variable for experimental field spikes, standard laboratory spiking and storage showed good recoveries.

b. *Quality assurance evaluation.* Their quality assurance (QA) effort, which involved spiking samples from all aquatic strata tested, was sound and provided valid QA for the environmental monitoring program. IAPEC contends that EPA's concern as to the insufficiency of a 29 percent recovery for "the phosphate esters spiked or sediment samples carried to the field and spiked in the field" is inappropriate. This description referred to early testing involving only six samples, whereas the overall experimental recovery rate was 70 percent.

c. *Location and selection of sampling sites.* Sample site selection was agreed upon by industry and EPA, the collections were conducted exactly as agreed upon, and calculated safety factors for each site (based on rainbow trout MATC) ranged from 2 to 10.

d. *Statistical treatment of data obtained.* Q-test was used to identify extraneous or outlying values in the water data set. All of the monitoring data were given to the Agency, including the raw data from the appendices of the monitoring report. Thus the Agency can apply whatever statistical treatment it considers appropriate.

e. *Analytical method.* All methods were validated according to state-of-the-art validation procedures. Information on methods, detection limits and quality assurance was provided to the Agency before the program began. IAPEC received no comments, questions or suggestions for changes.

f. *Interpretation of results.* This study provides evidence for no concern for exposure through the water column. IAPEC believes that aryl phosphates would be adsorbed to sediment and desorb very slowly, meaning that any potential environmental problems would be to sediment-dwelling organisms.

EPA Response. EPA is not proposing monitoring in this test rule.

Following the ANPR, EPA conducted a Good Laboratory Practices (GLP) Inspection/Study Audit Report on the aryl phosphate monitoring study (Ref. 68), which reported numerous GLP compliance deviations and reporting inconsistencies. In addition, while overall experimental recovery rate was 70 percent, the recovery for the field-spiked sediments was only 29 percent. The minimum recovery specified by the ACS guidelines for reliability (Ref. 2a) is 60 percent. A lower recovery could result in a large occurrence of false negative results. These shortcomings caused EPA to dismiss the monitoring report.

7. *Issue.* How useful is a site-specific aquatic ecotoxicity test procedure compared to standard laboratory ecological tests? Is there a need for terrestrial testing in addition to aquatic testing for a site-specific effect?

Comments. IAPEC commented that a site-specific test was not feasible, because in their monitoring study, five of the esters proposed for testing were not found in water, four were not found in sediment and three were not present in sediment or water. In addition, where aryl phosphates were found, the presence of other organic contaminants would dominate any effects of aryl phosphates. IAPEC held that conventional risk assessment using standardized protocols was preferable. It also contended terrestrial organism testing was not needed, as there was no significant exposure.

EPA Response. EPA is not proposing site-specific aquatic ecotoxicity testing in this test rule. EPA agrees with the comment on testing procedures. This proposed test rule includes standards for environmental testing and chemical fate studies. There has been some evidence of terrestrial exposure, particularly in the vicinity of aryl phosphate manufacturing plants (Ref. 18), but EPA is not proposing terrestrial testing at this time.

8. *Issue.* Should an oncogenicity testing requirement be based on results of selected mutagenicity tests or rather on a section 4(a)(1)(B) finding?

Comments. EDF concluded the use of mutagenicity data as the sole basis for choosing chemicals for oncogenicity testing was inappropriate, and stated that any chemical with substantial human exposure should be tested for oncogenicity and *in vitro* and *in vivo* mutagenicity. IAPEC and Stauffer doubted aryl phosphate exposure would support a section 4(a)(1)(B) finding, and IAPEC suggested that, because all mutagenicity information was negative, oncogenicity testing should not be considered.

EPA Response. NTP is performing a 2-year bioassay on TCP, and EPA will examine the results before deciding whether further oncogenicity testing on any other aryl phosphate is needed.

C. Substances to Which the Rule Applies

1. *Chemistry of aryl phosphates.* Aryl phosphate base stocks, as defined in Unit I.A of this preamble, are phosphate esters of phenol or of alkyl-substituted phenols. They are produced by reaction of a phenol, alkylated phenol, and/or an aliphatic alcohol with phosphorus oxychloride ($POCl_3$) at elevated temperatures in the presence of a catalyst. Mixed aryl phosphate esters are produced by reacting $POCl_3$ with controlled quantities of appropriate phenols. Variations in feedstock, starting proportions or reaction conditions will result in batch-to-batch differences that could account for disparities in the physical properties of these mixed esters (Refs. 42 and 50).

A second alkyl substituent in the starting phenol greatly increases the number of possible components in the final product; there are more than 50 for trixylyl (tris-dimethylphenyl) phosphate, for example. When the feedstock is a mixture of non-isomeric phenols, the possibilities may multiply even further.

The names applied to aryl phosphate base stocks can be confusing. For example, as described in Unit I.A of this preamble, a phenyl group can be alkylated in the ortho, meta, or para position, so that "tricresyl phosphate" [tritolyl phosphate, tri(methylphenyl) phosphate] could be either tri-meta-cresyl phosphate (TMCP) (one of the isomers), the corresponding triortho- (TOCP) or tri-para- (TPCP) ester, or a mixed ester where two or three of the cresyl isomers are present in the same molecule. In practice, because commercial TCP may be manufactured from a blend of ortho, meta, and para-cresol, it may contain up to 10 possible tricresyl phosphates, in proportions that depend not only on the proportions of starting cresol isomers, but also on their relative reactivity under the manufacturing conditions employed. So-called "tricresyl phosphate" is a complex substance containing TOCP, TMCP, and TPCP (though certain commercial mixtures may be primarily the para isomer with 1 percent or less of the ortho isomer), plus some dicresyl phenyl phosphate, cresyl diphenyl phosphate, and triphenylphosphate that reflect the presence of some unsubstituted phenol in the feedstock. If the complex substance is primarily TOCP, but contains some TMCP and TPCP, it is generally called TOCP.

2. *Category.* Under TSCA section 26, EPA has authority to take any action authorized or required to be taken with respect to a chemical substance or mixture with respect to a category of substances or mixtures. TSCA section 26(c)(2) defines "category of chemical substances" to mean

> a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances. Thus, the term "category of chemical substances" is quite broad.

This proposed rule would require testing of the aryl phosphate base stock category under sections 4(a)(1)(A) and (B) of TSCA for both existing members of the category and future entries to it. The category is based on chemical structure. EPA believes that the phosphotriester function common to all aryl phosphates justifies using toxicity data identifying a hazard for one aryl phosphate substance to suggest a hazard potential for other aryl phosphate

category members. In evaluating the testing needs for the aryl phosphate base stock category, EPA considered all available data, including: production volume; use; release; exposure; test data; information included in the ITC's report; TSCA section 8(a), (d) and (e) data; comments received following the publication of the ANPR; recent publications in the literature; any EPA-generated monitoring; and additional information.

EPA, by taking the category approach, will assure that any newly-manufactured aryl phosphate base stock meeting the category definition, such as chemicals on the TSCA Inventory but not being produced, or any aryl phosphate base stocks that are "new chemical substances" under TSCA section 5, would also be subject to the rule. This approach should preclude the necessity of a new test rule if changes in production processes yield differences in aryl phosphate components.

For instance, in a 1984 report by Muir (Ref. 50), cresyl diphenyl phosphate (CAS No. 26444-49-5) was given as the major component in two commercial phosphate esters, and the 1980-81 NOES (Ref. 52) reported 13,370 employees exposed to this substance. However, although this substance is on the TSCA Inventory, no production was reported in the 1986 Chemical Update System (CUS). Without the category finding, cresyl diphenyl phosphate production could easily be resumed without the substance being subject to testing.

3. *Test substances.* Promulgating a test rule for aryl phosphates raises several important policy issues. One of the most difficult is the question of what to test. Data may be difficult or impossible to evaluate if the test substances are not appropriately chosen and their composition not adequately specified.

EPA considered several different test substance options: individual isomers, aryl phosphate components of base stocks listed on the inventory, aryl phosphate base stocks, and commercial products.

a. *Individual isomers.* Because most aryl phosphate base stocks marketed are complex substances whose components may have varying toxicities, EPA considered requiring testing of each isomeric component. The Agency abandoned this approach because of the diversity of some complex substances such as trixylenyl phosphate, which may have 50 or more isomers. The cost and complexity of testing hundreds of isomers would be prohibitive, and the time required for such testing would significantly delay EPA's evaluation of the data.

b. *Base stock components.* The 1977 TSCA Non-Confidential Inventory includes 58 individual base stock components meeting the chemical definition (Ref. 55). Several of the 58 aryl phosphates on the inventory are components of the base stocks listed in this proposed test rule but are not reported in production. Although the number of inventory components is substantially less than the number of possible isomers, the same objections (high cost and testing program delays) apply. In addition, the benefits of such testing may be even fewer than for testing of individual isomers if the toxicity of aryl phosphates is an isomer-specific phenomenon.

c. *Commercial products.* EPA also rejected testing of commercial aryl phosphate products. These may be aryl phosphate base stocks or mixtures of aryl phosphate base stocks and other substances. Since EPA is interested in aryl phosphate toxicity it does not seem wise to test substances that may contain non-aryl phosphate components or that are mixtures of base stocks. In addition, the number, and often the complexity, of commercial products exceeds that of base stocks, making this a more expensive option.

d. *Base stocks.* EPA is proposing aryl phosphate base stocks as the test substances. EPA believes that this approach strikes a balance between the need to characterize aryl phosphate toxicity, the unacceptably high cost of the other options considered, and the potential difficulties of any case-by-case test substance selection process. Base stocks, as defined in this proposed rule, include all the individual aryl phosphates to which people or the environment may be exposed as a result of activities involving aryl phosphate base stocks or downstream aryl phosphate-containing consumer or industrial products. Finally, if test results on a base stock suggest a need for more detailed characterization, EPA can require by separate rulemaking testing of individual or combined aryl phosphates, guided by the analytical data and other results on all the base stocks initially tested. Thus, this proposed rule can be considered a type of screening rule.

The aryl phosphate base stocks now in production include seven of the nine aryl phosphates listed in the ANPR (see Unit I.B.2.a of this preamble). The other two, NDP and DBDP, are not being produced (Ref. 55) and thus would not be subject to the testing requirements unless production resumed. The more recent additions to the list of in-production category members are di(*n*-butyl) phenyl phosphate (DBP), and four aryl phosphate base stocks closely related to IDP and BDP.

Thus, the Agency has identified 12 members of the aryl phosphate base stock category that it believes to be in production (Ref. 55) for which it is proposing testing at this time. They are as follows (see Unit III.B of this preamble for more information):

i. *tert*-Butylphenyl diphenyl phosphate.
ii. bis-(*tert*-Butylphenyl) phenyl phosphate.
iii. tris-(*tert*-Butylphenyl) phosphate.
iv. Di-*n*-butyl phenyl phosphate.
v. 2-Ethylhexyl diphenyl phosphate.
vi. Isodecyl diphenyl phosphate.
vii. Isopropylphenyl diphenyl phosphate.
viii. bis-(Isopropylphenyl) phenyl phosphate.
ix. tris-(Isopropylphenyl) phosphate.
x. Tricresyl phosphate.
xi. Triphenyl phosphate.
xii. Trixylyl phosphate.

4. *TSCA section 8(a) reporting and triggering of testing.* EPA recognizes costs of the complete testing for some category members may be burdensome (see Unit V of this preamble) and has prioritized the proposed test requirements (see Unit III of this preamble). EPA believes most or all current manufacturers of base stocks can afford the tests in Level 1, some can support the additional tests in Level 2, and a few can afford Level 3 testing. For this reason, EPA proposes a trigger mechanism that ties testing requirements to specified production levels.

To facilitate this approach, EPA is proposing, under section 8(a) of TSCA, a Preliminary Assessment Information Rule (PAIR) to require annual reporting by manufacturers and importers of production and importation volumes for all substances meeting the definition of this chemical category which are now, or become, listed on the public or confidential portion of the TSCA Chemical Substances Inventory.

5. *Synergism and antagonism.* Synergism and antagonism among components may also affect the toxicity of the final product. To some extent this will be reflected in the testing of base stocks; however, testing expressly for these phenomena would require tests of individual components and combinations of components at different levels. The prohibitive cost of testing components individually (Unit I.C.3.a of this preamble) would also apply to any study of synergism and antagonism.

II. Findings

EPA is basing its proposed testing for members of the aryl phosphate category on the authority of sections 4(a)(1)(A)

and 4(a)(1)(B) of TSCA through the use of TSCA section 26(c).

A. Findings Under TSCA Section 4(a)(1)(B)(i)

Pursuant to section 4(a)(1)(B) of TSCA, EPA finds that aryl phosphate base stocks are produced in substantial quantities and that the use of aryl phosphate base stocks may result in substantial human exposure and/or substantial release to the environment.

Under TSCA section 26(c), EPA proposes to make a section 4(a)(1)(B) finding for the entire aryl phosphate base stock category, including (1) all such substances on the TSCA Inventory, both public and confidential, and (2) any substance not yet produced that would fit the definition of aryl phosphate base stocks (see Unit I.C.2 of this preamble).

EPA believes that this is an appropriate category of substances under section 26(c) because they are similar in molecular structure and in use and because their common phosphate triester functionality confers the potential for similar biological activity. This category is also "suitable for classification" because the ITC designated aryl phosphates as a category for priority consideration for testing.

EPA is developing a general policy under TSCA section 4(a)(1)(B) (the "B" policy) in which it will articulate its criteria for making findings under this provision. The "B" policy is being developed in response to the April 12, 1990, decision in *CMA v. EPA*, 899 F.2d 344 (5th Cir. 1990), in which the Court remanded the TSCA section 4 rule for cumene to EPA to "articulate the standards or criteria on the basis of which it found the quantities of cumene entering the environment from the facilities in question to be 'substantial' and human exposure potentially resulting to be 'substantial.'" Although not required to do so by the cumene decision, EPA also will be articulating the criteria for 'substantial production' and 'significant human exposure.' EPA has recently published the criteria for public comment (56 FR 32294).

EPA has decided to move forward in proposing this aryl phosphate test rule under both TSCA sections 4(a)(1)(B) and (A), without waiting for notice and comment on the generic "B" policy. The Court in CMA made it clear that EPA need not adopt a definition applicable to all cases, but may choose to proceed on a case-by-case basis, if it rationally explains its exercise of discretion. Thus, because this proposal articulates the criteria used in making findings under TSCA section 4(a)(1)(B) for aryl phosphate base stocks, it is not necessary to wait for publication of a generic policy before proposing this test rule.

TSCA does not provide EPA with much guidance on what criteria and standards to use in making "B" findings. The statute does not define the terms "significant" or "substantial." The policy section of TSCA, however, makes it clear that Congress considered testing of chemical substances to be an important aspect of the Act. This section provides:

> [that] adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures.

The legislative history of TSCA also provides some guidance on what criteria are to be used in making "B" findings. The legislative history states that "[t]he conditions specified in TSCA section 4(a)(1)(B) reflect the Committee's recognition that there are certain situations in which testing is desirable even though there is an absence of information indicating that the substance or mixture may be harmful." H.R. Rept. No. 1341, 94th Cong. 2d Sess. (1976), at 18 reprinted in, A Legislative History of the Toxic Substances Control Act (Comm. Print 1976) ("Leg. Hist.") at 425, and "there are certain situations in which testing should be conducted even though there is an absence of information indicating that the substance or mixture per se may be hazardous." H.R. Conf. Rept. No. 1679, 94th Cong. 2d Sess. (1976), reprinted in, Leg. Hist. at 674. The legislative history also provides that EPA "is not limited to consideration of sheer volume of production or exposure at a specific point in time. The duration of exposure, the level of intensity of exposure at various periods of time, the number of people exposed, or the extent of environmental exposure are among the considerations which may be relevant in particular circumstances." [Leg. Hist. at 425.] EPA believes that it is reasonable to interpret the duration of exposure and level of intensity of exposure as relating to "significant" human exposure, the number of people exposed as relating to "substantial" human exposure, and the extent of environmental exposure as relating to "substantial" environmental release.

EPA recognizes that it must not define "significant" and "substantial" in ways that would require the Administrator to make findings for every substance in commerce, or the statute would have simply required testing for all substances. Nevertheless, TSCA section 4(a)(1)(B) is designed to support risk management activities under the other provisions of TSCA. Thus, it is reasonable to interpret TSCA section 4(a)(1)(B) as authorizing EPA to require testing for every substance whose environmental or human exposure is of such magnitude or type that it may need to be regulated if test data reveal adverse effects.

EPA believes that, for this category of chemical substances in which certain members are structurally similar, may be used interchangeably, and in which some individual members of the category are produced in substantial quantities, it may be reasonable to require testing of a category of substances that collectively is or will be produced in substantial quantities, greater than 1 million pounds per year, and that either collectively may be released to the environment in substantial quantities, greater than 1 million pounds per year, or to which collectively there may be significant or substantial human exposure, over 1,000 workers, 10,000 consumers or 100,000 people. Furthermore, if EPA made findings only on individual substances that met the thresholds for substantial production, substantial release, and significant or substantial human exposure, persons subject to the rule could avoid providing the required data by switching to substances not in current production. Thus, EPA would have to propose another test rule every time a manufacturer switched to an aryl phosphate base stock not otherwise in production. Theoretically, the persons subject to the rule could continue switching the substances they make and process, and EPA would never catch up. To prevent this, EPA believes it is appropriate, in this special case, to make the findings for the category as a whole, using the same criteria for making such findings that would be used for individual chemical substances and mixtures. However, for other chemical categories EPA may decide not to make the substantial exposure or quantities finding for the category as a whole, instead considering exposure on a subcategory or individual chemical basis.

EPA specifically solicits comment on whether EPA should use the same section 4(a)(1)(B) finding numerical thresholds for a category of chemicals as are used for individual chemicals, or instead require higher thresholds. When this rule is promulgated, EPA will address all comments on the proposed criteria that are relevant to this rule as well as comments on this proposed rule.

1. EPA finds that the category of aryl phosphate base stocks is produced in substantial quantities. Manufacturers recently submitted production levels of individual category members to EPA as confidential business information. However, a nonconfidential EPA-estimated aggregate category production total of 72.1 million pounds is available (Ref. 6).

EPA is reserving discussion on what it considers to be the minimum production volume that can be considered "substantial" until it promulgates its "B" policy. Nevertheless, EPA finds that 72.1 million pounds per year clearly is above the minimum level that can be considered "substantial." EPA believes it is reasonable to interpret substantial production to mean large production, and that 72.1 million pounds is a large amount of production. Although EPA does not know the exact percentage of chemical substances in commerce with production volumes above 72.1 million pounds per year, the TSCA section 8(b) inventory of the substances in commerce shows that only 4.5 percent of the listed substances have production volumes over 10 million pounds, together accounting for over 95 percent of the total production of all substances produced in the United States (see 56 FR 32294, 15 July 1991). Moreover, the inventory shows that only about 1.5 percent of the listed chemical substances in commerce have production volumes over 100 million pounds per year. Thus, EPA believes that substances with production volumes of at least 72.1 million pounds per year comprise somewhere between 1.5 percent and 4.5 percent of the substances in commerce, and together account for over 95 percent of the total production of all substances produced in the United States. EPA believes that it is reasonable to conclude that this small group of substances (i.e., the top 1.5 to 4.5 percent according to production volume), which account for the vast majority of all production, clearly are substances with substantial production.

2. EPA finds that the use of aryl phosphate base stocks in various products results in substantial human exposure to these base stocks. Aryl phosphate base stock components generally comprise 0.5 to 20 parts per hundred parts of resin, or up to 45 percent by weight of plastic formulations (Ref. 73), and 0.5 to 100 percent of functional fluids (Ref. 35) (0.5 to 4 percent as antiwear additives and 100 percent as hydraulic fluids).

Exposure potential in the workplace is substantial. The 1980 National Occupational Hazard Survey (NOHS) update indicates more than 2 million workers are exposed to aryl phosphate base stock components (Ref. 51). Although it is difficult to evaluate exposure numbers in subsequent data, e.g., NOES (Ref. 52), because of inconsistent reporting terminology (see Unit I.D.2 of this preamble), EPA does not know of any reason why the number of workers would have changed significantly between 1980 and 1991.

Exposure in the workplace occurs via inhalation and dermal contact. While most of the aryl phosphate base stocks are high boiling-point liquids, they may be volatile or form aerosols in certain applications. For example, a NIOSH walk-through of a General Motors Die Cast Department in Rochester, NY, in which aryl phosphate-containing hydraulic fluids were used at 100 °F, found TPP and IPP at concentrations of 0.57 and 0.013 mg/m^3, respectively (Ref. 75).

EPA estimates workers having dermal exposure to aryl phosphate base stocks may have 1300 to 3900 mg/day exposure if no protective clothing is worn (Ref. 35). Aircraft maintenance workers frequently work with hydraulic fluids and may be at particular risk. EPA described this exposure pattern in its proposed test rule for TBP (Ref. 71). The Tributyl Phosphate Task Force, an industry group, sponsored a survey of aircraft worker exposure to tributyl phosphate, and provided estimates that 2,200 employees in this industry are routinely exposed to aircraft hydraulic fluid and 43,000 mechanics may, at various times, be exposed (Ref. 34). EPA believes exposure estimates provided for users of aircraft hydraulic fluids containing TBP are applicable to users of those containing aryl phosphate base stocks, as the applications of some of the aryl phosphate base stocks are similar.

Some of these functional fluids are manufactured to meet military specifications. Responding to a recent query by EPA, the U.S. Army responded that there was potential TOCP exposure at 19 bases involving 196 military and 146 civilian workers (Ref. 74).

In addition to worker exposure, the general population uses plastic in many forms and is potentially exposed to aryl phosphates from base stocks used as plasticizers. The heat in a closed automobile can volatilize plasticizers used in upholstery or other plastic components, and has been shown to produce a visible film of TCP on the inside of automobile windshields (Ref. 17). This means millions of Americans may be inhaling TCP in automobiles on a regular basis, particularly on hot days. Room temperature water can leach plasticizers out of plastics (Refs. 2 and 7). Thus, people who drink out of plastic glasses, wash plastic items or handle any such plastic items containing aryl phosphate plasticizers, may be exposed to aryl phosphates through that water.

Disposal of plastics generates additional general population exposure potential, as aryl phosphates may leach out of plastics in landfills and enter groundwater (Ref. 7). Thus, human populations near landfills may be exposed to aryl phosphates in their drinking water. Incineration may cause aryl phosphates to volatilize (Ref. 7), potentially causing populations of people living near incinerators to be exposed to aryl phosphates in the air. One EPA report has postulated that as much as 80 percent of plasticizers may volatilize or leach out (Ref. 73). General population exposure is further confirmed by the detection of aryl phosphates in human adipose tissue (Ref. 64).

EPA believes that it is reasonable to interpret the term "substantial human exposure" to mean widespread human exposure, or in other words, exposure of a large number of people. EPA believes that exposure of 2 million workers is substantial exposure because, where millions of workers are exposed to a chemical substance, it is reasonable that EPA should have data on the potential hazards associated with the substance so that EPA can implement appropriate risk management efforts where necessary to protect workers against unreasonable risk. As a general matter, EPA has found that workers tend to be subject to routine or episodic exposure over a long period of time. The Court in CMA recognized that there could be some overlap between substantial and significant human exposure: "it is not necessarily clear that 'significant' and 'substantial' as used in clause (II) must be understood in a way that prevents their respective meanings or requires that any factor relevant to one may be necessarily irrelevant to the other." CMA at 356, note 17. Thus, exposure, to be considered substantial, does not have to be as widespread for workers as for consumers or the general population. EPA believes that exposure of 2 million workers is widespread enough to necessitate testing for the potential hazards of the substances to evaluate whether worker protection efforts are necessary.

Moreover, EPA believes that millions of consumers may be exposed to aryl phosphate base stocks due to their presence in plastics and that millions of members of the general population may be exposed to aryl phosphate base

stocks that leach out of plastics in landfills and are released into the air during incineration of plastics. EPA believes that potential exposure of millions of consumers and members of the general public to aryl phosphates is substantial exposure because where millions of people are exposed to chemical substances, it is reasonable that EPA should have data on the potential hazards associated with the substance so that EPA can implement appropriate risk management efforts where necessary to protect consumers and members of the general public against unreasonable risk.

3. EPA finds that aryl phosphate base stocks used in various products are released to the environment in substantial quantities. An EPA report estimated that 1 to 3 million pounds of aryl phosphate base stocks may enter the environment annually (Ref. 42).

TPP has been detected in surface waters from the San Francisco Bay (Ref. 39) to the Delaware River (Ref. 60). Los Angeles rainwater was found to contain TPP (Ref. 33). A 1986 survey found TPP in at least three major waterways, in both sediment and fish (Ref. 72). Substantial release is indicated by the presence of aryl phosphates (TPP, IPP, TXP, TCP) in water (Refs. 31, 39, 41, and 60), sediment (Refs. 39, 18, 31, 41, and 72) and fish (Refs. 37, 39, and 72).

IPP was detected in soil and vegetation samples near production sites (Ref. 18).

The presence of TPP and EDP in foodstuffs (Refs. 19, 26, 27, 28, and 29) and of TPP in human adipose tissue (Ref. 64) suggests the possibility of ingestion of these chemicals.

TPP has been found in the water-extractable fraction from items such as plastic car upholstery (Ref. 2). Disposal of such plastics through landfills or incineration adds to environmental exposure, as leaching of plasticizers or volatilization may occur (see Unit II.A.2 of this preamble).

4. Evidence for substantial production, substantial human exposure and substantial environmental release. EPA believes that the phrase "released into the environment in substantial amounts" is intended to capture substances with extensive release to the environment, which in itself would be sufficient reason to require testing in the absence of any information that the substance may be hazardous to human health or the environment. In other words, as with substantial production, release of substantial quantities means large release. Aryl phosphate base stocks are released into the environment in quantities of 1 million to 3 million pounds per year. EPA finds that 1 million to 3 million pounds of release to the environment is a sufficiently large release that EPA should require testing to determine whether measures should be taken to reduce risk to the environment. Moreover, the Toxics Release Inventory (TRI), under the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. section 11023, shows that 37 percent of the listed substances have releases over 1 million pounds, accounting for over 99 percent of the total reported releases on the TRI by volume released. Because the TRI does not include all substances, less than 37 percent of all substances would have releases above 1 million pounds. EPA believes that it is reasonable to conclude that this small group of substances (i.e., less than 37 percent), which accounts for over 99 percent of all releases, clearly are substances with substantial releases.

B. Findings Under TSCA Section 4(a)(1)(A)(i)

Pursuant to section 4(a)(1)(A)(i) of TSCA, EPA finds that the manufacturing, processing, use, distribution in commerce, and disposal of aryl phosphate base stocks used in various products may present an unreasonable risk of injury to human health and the environment.

1. *Evidence of potential for adverse human health effects.* Subchronic toxicity testing of TPP, the most acutely toxic aryl phosphate, demonstrates effects in liver, kidney and adrenals (Ref. 30). TCP demonstrates the same toxicities as TPP (liver, Refs. 30 and 54; kidney and adrenals, Refs. 54 and 59), and also affects the immune system (Ref. 10). Long-term treatment with DBP damages liver, kidneys and blood (Refs. 46 and 49). Santicizer 148 (a mixture of 87 to 91 percent isodecyl diphenyl phosphate, 5 to 7 percent di(isodecyl) phenyl phosphate and 4 to 6 percent TPP) affects both the liver and the hematologic system (Ref. 48).

Since the 1930s, various individual and combined aryl phosphates have demonstrated neurotoxicity, including phenol-type syndrome (muscular tremors, hyperexcitability, spastic rigidity, muscular weakness and generalized flaccid paralysis, perhaps due to degradation to the phenol or cresol) (Refs. 62), as well as OPIDN, the well-known human syndrome caused by certain individual aryl phosphates (see Ref. 32). Several cases in humans, primarily due to the tricresyl phosphates, have been reported (see Ref. 1). Studies performed on individual tricresyl phosphate isomers indicated the major neurotoxicant was TOCP (Refs. 61 and 63). Manufacturers, therefore, reduced the TOCP content of their products. However, a recently submitted TSCA section 8(e) hen study (Ref. 40) indicates that complex TCP-containing aryl phosphates containing less than 0.1 percent TOCP have neurotoxic effects similar to those arising from exposure to pure TOCP.

Three recent studies have demonstrated the reproductive toxicity of TCP in several species and strains of laboratory animals (Refs. 12, 13 and 15). The NTP and NIEHS studies both used TCP with less than 0.1 percent TOCP, while EPA's study used TCP with less than 9 percent TOCP. All three studies showed effects on male reproductive parameters, and histopathologic effects were seen in the ovaries in the EPA-sponsored study. Both the EPA-sponsored and NIEHS-sponsored studies demonstrated developmental toxicity, while the NIEHS study also showed reproductive effects in the F_1 generation at the lowest dose.

A two-generation reproductive and fertility study has also been performed on dibutyl phenyl phosphate (Ref. 29a). In the F_0 generation survivability of pups was decreased in both the mid-level and high dose, while in the F_1 generation, only the high dose was so affected.

A confidential TSCA section 8(e) study was submitted to EPA in 1990 demonstrating similar reproductive effects with an additional aryl phosphate.

TOCP has been tested in a standard rat developmental toxicity study (Ref. 67), with significant increases in mean pup body weight at doses as low as 87.5 mg/kg. Further, the two-generation reproductive study on TCP in mice showed significant developmental effects in the pups, with decreases in litter size and live-born pups as well as decreased body weight (Ref. 15). A one-generation study in Long-Evans rats with TCP (Ref. 12) also indicated developmental toxicity effects: decreases in percent of mothers delivering live-born young, and decreases in litter size and pup viability.

2. *Evidence of potential for environmental toxicity.* Mayer et al. (1981) reported rainbow trout exposed to Pydraul 50E (aryl phosphate-containing hydraulic fluid), Pydraul 115E (aryl phosphate-containing hydraulic fluid), or either of their major aryl phosphate components, NDP and cumylphenyl diphenyl phosphate (CDP), developed cataracts after 90 days' exposure. These complex substances also affected bone development and bone collagen content. Reduced growth and survival rates were seen with the two mixtures and also with CDP. With Pydraul 115E, exposure

to 16 μg/L (microgram/liter) and above also caused impaired swimming and feeding activities. This study also examined lake trout fed Pydraul 50E for 120 days and observed cataract effects and growth reduction at 5 μg/L, and effects on vertebral collagen at 2.6 μg/L. Growth and survival were affected in fathead minnows exposed to Pydraul 50E for 30 days at 752 μg/L. Precursors to eye cataracts were seen histologically at 317 μg/L. The most sensitive endpoint in this series of tests was the reduced vertebral collagen in rainbow trout following 90 days of exposure to CDP at 0.22 μg/L (Ref. 39).

A 4-month feeding study on Pliabrac 521, an aryl phosphate containing TPP, TCP, TXP and cresyl diphenyl phosphate, indicated reproductive toxicity in the minnow (Phoxinus phoxinus) (Ref. 5).

A 4-month exposure to IMOL S-140 (composed of TCP, TXP, and assorted other phosphates) in rainbow trout resulted in chronic toxicity, indicated by altered feeding behavior, increased serum enzyme levels of serum glutamic transaminase and lactic dehydrogenase (LDH), presence of muscle LDH in serum and discoloration of internal fatty tissue (Ref. 36).

Ninety-day studies in the fathead minnow for several aryl phosphate base stocks showed differing responses (Ref. 16). The authors indicated that for Santicizer 148 (IDP, TPP), the most sensitive endpoint was growth, while for Fyrquel GT (BDP, TPP), Phosflex 31P (TPP, IPP), and Pydraul 50E (NDP, CDP), the most sensitive endpoint was survival. Gross observation of the minnows did not demonstrate the cataract problems reported in 1981 by Mayer et al. (Ref. 39).

3. *Evidence of potential for unreasonable risk.* In determining that a substance may present an unreasonable risk, EPA must consider both the potential hazard of the substance and the potential for human and environmental exposure to the substance. EPA estimates that 2 million workers and additional millions of consumers and members of the general population may be exposed to aryl phosphate base stocks. In fact, EPA finds that the amount of human exposure to aryl phosphate base stocks is substantial. It is not necessary for human exposure to be "substantial" to support a finding of potential unreasonable risk. Nevertheless, where human substantial exposure does exist, that exposure necessarily is widespread enough to support the exposure component of a potential risk finding. As discussed above, aryl phosphates have been shown to cause human neurotoxicity, and the potential for others such as liver, kidney, adrenal and blood effects, reproductive toxicity and developmental toxicity. The widespread human exposure coupled with the potential human hazards associated with aryl phosphates indicates that aryl phosphate base stocks may present a risk to human health.

EPA estimates aryl phosphate base stocks are released into the environment in quantities of 1 million to 3 million pounds per year. In fact, EPA finds that 1 million to 3 million pounds of aryl phosphate base stocks released into the environment per year constitutes substantial release into the environment. It is not necessary for release into the environment to be "substantial" release to support a finding of potential unreasonable risk to the environment. Nevertheless, where substantial release into the environment exists, that release necessarily is large enough to support the exposure component of the potential risk finding. As discussed above, aryl phosphate base stocks have been shown to cause cataracts, reduced growth and survival rates, impaired swimming and feeding activity, reproductive toxicity, chronic toxicity, and reduced vertebral collagen in fish. The large release into the environment coupled with the potential environmental hazards associated with aryl phosphate base stocks indicates that aryl phosphate base stocks may present a risk to the environment.

From the information presented above on the hazard potential of aryl phosphate base stocks and the amount of potential human and environmental exposure to aryl phosphate base stocks that are used in various products, EPA finds that the manufacturing, processing, use, distribution in commerce, and disposal of aryl phosphate base stocks may present an unreasonable risk of injury to human health and the environment.

C. Findings Under TSCA Section 4(a)(1)(A)(ii) and (B)(ii)

Pursuant to section 4(a)(1)(A)(ii) and (B)(ii) of TSCA, EPA finds that, for all substances comprising the aryl phosphate base stock category, data are insufficient to determine or predict the effects of manufacturing, processing, distribution in commerce, or use of these substances on health and on the environment.

In evaluating the testing needs for the aryl phosphate base stock category, EPA considered all available data including information in the ITC's report, TSCA section 8(d) and 8(e) data, comments received following the publication of the ANPR, and recent scientific publications. An EPA review (Ref. 66) of information available through early 1987 is available. Later sources are included in the docket for this rulemaking.

Without more complete information regarding what was actually tested, and in some cases, how the studies were performed, none of the studies discussed in Unit II.B of this preamble are acceptable to EPA for the purpose of risk assessment.

1. *Subchronic effects.* Monsanto submitted a 3-month feeding study on DBP with Sprague-Dawley rats in March 1987 (Ref. 49). The study was not conducted according to EPA guidelines, as EPA's GLPs require a detailed analysis of all components in the tested compound. However, the report only identified the components (DBP, butyl diphenyl phosphate and TBP) and gave no percentage composition. Analyses of test material in food reported only the levels of DBP.

Similarly, two other subchronic studies, one on TCP (Ref. 59) and the other on Santicizer 148 (Ref. 48), appear to meet the Agency's guidelines (or their equivalent), but inadequate test substance identification.

A subchronic study on *tert*-butylphenyl diphenyl phosphate (Ref. 43) may have an appropriate test protocol, but the high dose (1000 ppm in the diet) induced no treatment-related effects. EPA guidelines require that the high dose for a subchronic study induce some significant toxicity. In lieu of this EPA needs evidence that an appropriate high dose level was selected. In some cases EPA has accepted studies that use a level that exceeds potential human exposure by at least a factor of a hundred. These conditions have not been met for this study.

2. *Neurotoxicity.* Standard acute hen studies demonstrated OPIDN for TCP, TXP and IPP. Subsequently, FMC conducted a 90-day subchronic assay in the hen with Kronitex 50 (IPP) that may have been sufficient to reasonably predict or determine IPP neurotoxicity, but information on the material tested was insufficient for EPA to evaluate the study. The study in question describes the material tested simply as C8096-126-1 Phosphate Ester from FMC. However, FMC's cover letter stated this was Kronitex 50 (Ref. 24). The Material Safety Data Sheet (MSDS) (Ref. 25) gives the composition of Kronitex 50 as phenol, isopropylated, phosphate (3-1) (Cas No. 68937-41-7). EPA has three technical listings of the chemical analysis of Kronitex 50 (none associated with this study): two from the manufacturer (Refs. 20 and 21) and one from the published literature (Ref. 53).

The three listings are significantly different. For instance, the level of triphenyl phosphate in the three papers ranges from 24.9 to 33 percent. This difference may not affect the final toxicity result, but EPA is requesting comment on this issue (Unit IV.A.1 of this preamble).

A multi-dose study of TOCP has been performed in England, but published data on the methodology do not give enough information for EPA's needs (Refs. 56 and 57).

Acute neurotoxicity results on the *tert*-butylphenyl phosphates are mixed. Of the 12 studies on various forms of *tert*-butylphenyl phosphate, 7 are negative but 5 show diverse levels of OPIDN (Refs. 22, 23, 44, and 65 [two reported in Ref. 22]).

EPA does not propose repeating acute hen neurotoxicity studies for those aryl phosphate base stocks for which acceptable studies have already been completed and reviewed for the ANPR. However, DBP, one of the chemicals subject to this proposed rule, was acutely tested by Industrial Bio-Test. Tests carried out by the latter laboratory are questionable, but if the results were independently and appropriately audited, and the test substance adequately defined, EPA will decide if it is acceptable or whether further testing is required.

3. *Reproductive effects.* A two-generation reproductive study on TCP has been performed by NIEHS (Ref. 15). This was a continuous breeding study in mice using TCP with less than 0.1 percent TOCP. Reproductive effects were seen in both sexes, with sperm motility decreases seen in the F_1 generation at the lowest dose tested. A recent section 8(e) study (claimed as CBI) on another aryl phosphate base stock showed similar effects.

A two-generation reproductive and fertility study has also been performed on dibutyl phenyl phosphate (Ref. 29a). This study also was done using EPA guidelines, except for lack of information on the test substance. In the F_0 generation survivability of pups was decreased in both the mid-level dose and the high dose, while in the F_1 generation, only the high dose was so affected.

These studies may be acceptable to EPA for risk assessment if submitters can demonstrate that the test substances used were equivalent to what is now manufactured.

The studies on developmental toxicity submitted to EPA also lack adequate identification of test substance. Monsanto reported on studies for two plasticizers, Santicizer 141 and Santicizer 148 (Ref. 58). The study protocols are adequate, but the 3000 mg/kg/day high dose for the Santicizer 148 did not cause significant maternal toxicity. EPA guidelines require that significant maternal toxicity be elicited at the highest dose, to determine whether developmental toxicity will occur at levels below those that are toxic to the mother. That is, if no developmental effects are seen, then regulating the dose affecting the mother will protect the child. As with the subchronic toxicity guidelines, if the dose is high enough to guarantee a hundred-fold level above potential human exposure, then EPA may consider the study adequate.

Monsanto performed two additional developmental toxicity studies, on Santicizer 154 (Ref. 47) and BDP (Ref. 45), but neither produced maternal toxicity.

4. *Environmental effects.* EPA believes acute fish toxicity information is adequate for the substances tested. Because information from the ELS testing will include acute range-finding data, EPA is not proposing acute toxicity testing for untested aryl phosphate base stocks. However, data on long-term effects are deficient, and more information is needed for risk assessment. Fish toxicity data discussed in Unit II.B of this preamble are primarily from European studies on marketed products; the test substances for which analytical information was provided did not appear to include any aryl phosphate base stocks presently marketed in the United States.

D. Findings Unders TSCA Sections 4(a)(1)(A)(iii) and (B)(iii)

Pursuant to section 4(a)(1)(A)(iii) and (B)(iii) of TSCA, EPA finds that testing of these substances is necessary to determine or predict the effects of manufacturing, processing, use, distribution in commerce and disposal of all substances in the aryl phosphate base stocks category.

Under section 4(a)(1)(A)(iii) and (B)(iii), EPA finds that testing aryl phosphate base stocks is necessary to develop data for chemical analysis, organophosphorus-induced delayed neuropathy, two-generation reproductive and fertility effects, 120-day post-hatch rainbow trout ELS effects, anaerobic biodegradation, chronic Daphnia toxicity, subchronic toxicity, aerobic biodegradation, microcosm effects, subchronic neurotoxicity and developmental toxicity. EPA believes that data resulting from this testing will be relevant to a determination as to whether manufacturing, processing, distribution in commerce, use and disposal of aryl phosphate base stocks does or does not present an unreasonable risk of injury to health or the environment.

III. Proposed Rule

A. Proposed Testing and Test Standards

On the basis of the findings in Unit II of this preamble, EPA is proposing a test rule for aryl phosphate base stocks that meet the category definition specified in Unit I.A of this preamble.

This would be a two-stage test rule. First, the rule would require submission of chemical analysis data obtained by GC/MS. EPA would require for first-stage information any individual aryl phosphate positional isomer, except TOCP, or any other substance present in a base stock, to be identified and quantitated if present at a concentration of 1 percent or greater; quantitation for TOCP would be required to ±0.5 percent. TOCP would have to be quantitated, to ±0.05 percent, unless present at less than 0.10 percent. The Agency would notify manufacturers by certified mail if: (1) A particular chemical to be tested demonstrates equivalence to another manufacturer's product and testing costs may be shared; or, (2) the chemical in question does not demonstrate equivalence to another aryl phosphate base stock and testing costs may not be shared.

EPA would evaluate the analytical chemistry data and determine whether any base stock is equivalent to another. EPA proposes as equivalence criteria that any two base stock substances be considered equivalent if all the individual aryl phosphate components of the two substances are within 2 percent of each other, unless, for a situation involving three or more base stocks, this results in a range greater than 4 percent for any component. In such a case, EPA would apply its best scientific judgement.

Because of the economic impact of certain of these tests on some category members, EPA has prioritized the second-stage tests, providing three levels of testing. Level 1 is the base set of required testing for aryl phosphate base stocks having aggregate annual production volumes of at least 1 but less than 5 million pounds: 120-day post-hatch rainbow trout ELS test; three hen neurotoxicity tests — acute neurotoxic esterase (NTE), acute organophosphate delayed neuropathy, and subchronic organophosphate delayed neuropathy (triggered by a positive NTE or positive acute OPIDN study); and a two-generation reproductive test. Level 2 includes additional tests required for

aryl phosphate base stocks having aggregate annual production volumes of at least 5 but less than 10 million pounds: anaerobic biodegradation; chronic Daphnia; and subchronic toxicity. Level 3 includes additional testing for aryl phosphate base stocks having aggregate annual production volumes of at least 10 million pounds: aerobic biodegradation; microcosm; developmental toxicity; subchronic rat neurotoxicity - functional observation battery (FOB), motor activity (MA) and neuropathology (NP). EPA would notify manufacturers when they meet trigger levels, as determined from the proposed section 8(a) production reporting. Present and future aryl phosphate base stock manufacturers would be subject to testing requirements.

Proposed Test Standards	CFR citations
Level 1	
120-Day post-hatch trout ELS.	40 CFR 797.1600
Neurotoxicity in the hen	
Acute NTE	40 CFR 798.6450
Acute OPIDN	40 CFR 798.6540
Subchronic OPIDN, if triggered.	40 CFR 798.6560
Two-generation reproduction and fertility effects.	40 CFR 798.4700
Level 2	
Anaerobic biodegradation	40 CFR 796.3140
Chronic Daphnia	40 CFR 797.1350
Subchronic toxicity	40 CFR 798.2650
Level 3	
Aerobic biodegradation	40 CFR 799.700 (Bourquin paper (Ref. 9) incorporated by reference)
Microcosm ecosystem	§ 797.3050 (proposed)
Neurotoxicity in the rat: (may be combined with subchronic per specific guideline instruction; FOB and MA acute testing required).	
FOB	40 CFR 798.6050
MA	40 CFR 798.6200
NP	40 CFR 798.6400
Developmental toxicity	40 CFR 798.4900

The original ITC designation also recommended EPA investigate mutagenicity and oncogenicity and conduct epidemiology studies. However, considerable mutagenicity testing on aryl phosphates before and after the ANPR has been predominately negative, and EPA is not proposing such testing at this time. NTP is testing TCP for oncogenicity, and EPA has decided to await the outcome of this study before deciding if oncogenicity testing on other aryl phosphate base stocks is necessary. Any subsequent oncogenicity requirement would be the subject of a separate rulemaking. Epidemiology is discussed in Unit IV.5 of this preamble.

New aryl phosphate base stocks subject to TSCA section 5 would also be subject to this rule. Section 5(b) of TSCA requires that if a person submits a notice to EPA under section 5(a)(1) before the manufacture or processing of a chemical substance, and the substance is subject to a section 4 test rule promulgated before the submission of such notice, the data required by the section 4 test rule shall be submitted at the same time notice is submitted in accordance with section 5(a)(1). In other words, anyone making a "new" aryl phosphate base stock must first do the chemical analysis under § 799.700(e) and submit that analysis with the premanufacture notification to comply with § 799.700(c)(2). New chemical manufacturers will not be required to do tiered testing, however, until EPA has evaluated the chemical analysis data and determined if that aryl phosphate base stock is equivalent to any other substance, and if an aggregate production volume triggering stage 2 testing for that group of equivalent substances has been met. If, at the time a final test rule is promulgated, a substance has already been submitted to EPA and is being reviewed pursuant to section 5(a), EPA requires that the submitter provide the data required by this test rule. Category members subject to a section 5(e) order (i.e., already reviewed by EPA and being regulated) will be re-reviewed by EPA to determine if data required by the test rule are necessary.

B. Test Substances

All aryl phosphate base stocks, as defined by this rule, would be subject to this test rule. EPA has identified 12 aryl phosphate base stocks that are in production at this time (Ref. 55). Base stocks differing from one another by more than 2 percent in a single component (0.1 percent for TOCP) would be considered different base stocks for purposes of this rule. Any other base stock meeting the definition of aryl phosphate base stocks that EPA is not aware of or that comes into production in the future would also be subject to this test rule. See Unit I.C.3.d of this preamble for a more complete discussion of the background and decisions for the following substance listings.

The 12 aryl phosphate base stocks EPA believes are in production are as follows:

1. *tert*-Butylphenyl diphenyl phosphate (CAS No. 56803-37-3) or isobutylenated phenol, phosphate (3:1) (CAS No. 68937-40-6) (based on a 1:3 mol ratio isobutylene to phenol).

2. bis-(*tert*-Butylphenyl) phenyl phosphate (CAS No. 65652-41-7)or isobutylenated phenol, phosphate (3:1) (CAS No. 68937-40-6) (based on a 2:3 mol ratio isobutylene to phenol).

3. tris-(*tert*-Butylphenyl) phosphate (CAS No. 78-33-1) or isobutylenated phenol, phosphate (CAS No. 68937-40-6) (based on a 1:1 mol ratio isobutylene to phenol).

4. Di(*n*-butyl) phenyl phosphate (CAS No. 2528-36-1).

5. 2-Ethylhexyl diphenyl phosphate (CAS No. 1241-94-7).

6. Isodecyl diphenyl phosphate (CAS No. 29761-21-5).

7. Isopropylphenyl diphenyl phosphate (CAS No. 28108-99-8) or phenol, isopropylated, phosphate (3:1) (CAS No. 68937-41-7) (based on a 1:3 mol ratio propylene to phenol).

8. bis-(Isopropylphenyl) phenyl phosphate (CAS No. 28109-00-4) or phenol, isopropylated, phosphate (3:1) (CAS No. 68937-41-7) (based on a 2:3 mol ratio propylene to phenol).

9. tris-(Isopropylphenyl) phosphate or phenol, isopropylated, phosphate (3:1) (CAS No. 68937-41-7) (based on a 1:1 mol ratio propylene to phenol).

10. Tricresyl phosphate (CAS No. 1330-78-5), or tar acids, cresylic, phenyl phosphate (CAS No. 68952-35-2).

11. Triphenyl phosphate (CAS No. 115-86-6).

12. Trixylyl phosphate (CAS No. 25155-23-1) or tar acids, cresylic, C-8 rich, phenyl phosphate (CAS No. 68952-33-6).

For this proposed rule, EPA would not require testing of pure chemicals, but rather the base stocks to which persons (manufacturing workers, users, consumers, general populace, etc.), or the environment are actually exposed. EPA would require chemical analysis as the first stage of testing to help define equivalence for category members.

Any substance meeting the aryl phosphate base stock category definition, even if not named in the final rule, would be considered a member of this category and subject to this test rule.

C. Persons Required to Test

Because of the findings in Unit II of this preamble, EPA is proposing that persons who manufacture (including persons who import) or process or intend to manufacture and/or process an aryl phosphate base stock as defined by this rule, at any time from the effective date of the final test rule to the end of the reimbursement period, be subject to the testing requirements

contained in this proposed rule. This period is defined in 40 CFR 791.3(h).

Each manufacturer of a specific aryl phosphate base stock would pay a pro rata share of the aggregate cost of testing that specific test substance in proportion to its market share. Manufacturers (including importers) potentially subject to this rule should consult the procedures in 40 CFR part 790. As explained in 40 CFR part 790, initially manufacturers, but not processors, of one or more of these substances would be required to submit letters of intent or exemption applications. Pursuant to a recent amendment to part 790, small quantity research and development manufacturers are not required to submit letters of intent or exemption applications. Such manufacturers should consult the **Federal Register** at 55 FR 18881, May 7, 1990, for further details.

Product compositions may change because of feedstock or processing changes, and the toxicity of individual aryl phosphate components can vary widely. For this reason, chemical analysis data are needed to define the test substance and to prove equivalence of products if there are two or more manufacturers. As new manufacturers move into the market, they would also have to demonstrate equivalence, or conduct testing. The Stage 1 chemical analysis would be required for each in-production aryl phosphate base stock in this category.

D. Reporting Requirements

As required under 40 CFR 799.10, EPA is proposing that all data developed under this rule must be reported in accordance with its GLP standards which appear in 40 CFR part 792.

As required by TSCA section 4(b)(1)(c), EPA is proposing specific reporting requirements for each of the proposed test standards as follows: Final reports for the first stage of this test rule, the chemical analysis data, would be due no later than 6 months after the date of publication of the final rule.

Final reports for second stage studies would be due at intervals specified below following the notification of manufacturers by EPA by certified mail that the second stage of testing should begin on their substance or that production volume had triggered another level of testing.

Proposed Test Standards	Reporting Requirements
Level 1	
120-Day post-hatch trout ELS	18 months
Neurotoxicity in the hen	
Acute NTE	6 months
Acute OPIDN	6 months
Subchronic OPIDN	18 months
Two-generation reproduction and fertility effects	24 months
Level 2	
Anaerobic biodegradation	12 months
Chronic Daphnia	12 months
Subchronic toxicity	18 months
Level 3	
Aerobic biodegradation	12 months
Microcosm ecosystem	24 months
Neurotoxicity in the rat: (may be combined with subchronic per specificguideline instruction; FOB and MA acute testing required).	
FOB	18 months
MA	18 months
NP	18 months
Developmental toxicity	12 months

Progress reports on these tests would have to be submitted to EPA every 6 months, beginning 6 months after EPA notifies the manufacturers testing must proceed, until the final report is submitted.

TSCA section 14(b) governs EPA's disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, EPA will publish a notice of receipt in the Federal Register as required by section 4(d) of TSCA.

IV. Issues for Comment

A. Issues Relating to Choice of Test Substances

1. EPA requests comments on EPA's approach to choosing test substances.

Most aryl phosphate toxicity testing has been performed on multicomponent technical grade substances. EPA considered requiring testing of individual components because the literature has documented differences in toxicity between components and between individual isomers, but rejected this approach as impractical and too expensive. Instead EPA is proposing to require testing of aryl phosphate base stocks. These may vary significantly from manufacturer to manufacturer and perhaps between batches. EPA is proposing that base stocks differing from one another by more than 2 percent in a single component (0.1 percent for TOCP) be considered different base stocks for purposes of this rule. Would this result in an unnecessary or burdensome amount of base stock testing? Are there better ways or more appropriate criteria to define and differentiate base stocks?

2. How should the specific test substances be chosen?

EPA is proposing the first stage of this two-stage rule to enable the Agency to assess the identity and proportions of constituents of individually manufactured aryl phosphate base stocks. EPA is addressing this issue up front rather than through the exemption application process. To assure equitable sharing of second-stage testing responsibilities and costs among manufacturers in cases where multiple manufacturers produce aryl phosphate base stocks judged by EPA to be equivalent, the Agency would have three alternative courses of action, as follows:

- To have EPA or the manufacturers choose one of equivalent substances for testing.

• To require testing of a composite mixture of equivalent aryl phosphate base stocks.

• To define a "standard" test substance for each group of equivalent substances.

EPA is proposing in this Notice that EPA will choose one of the equivalent substances for testing, but desires comment on this.

3. What level of quantitation should EPA require in the chemical analysis? Should there be a requirement to quantitate any chemical component other than TOCP of an aryl phosphate base stock more precisely than ±2.0 percent?

Except for TOCP, the rule would require chemical analysis with identification of all components of the manufacturers' products present at a level of 1.0 percent or greater. However, data reported in Ref. 40 suggest that observed neurotoxicity from TCP may be due to TOCP present at less than 0.1 percent. Thus, the Agency is proposing to require quantification for TOCP if its concentration is 0.10 percent or greater. For comparison, the Office of Pesticide Programs (OPP) requires identification of all chemicals present in the test material at or above 1.0 percent concentration.

4. How detailed should EPA make the chemical analysis requirement, and what are the most useful techniques? Should EPA allow each submitter to supply justification for the methods he chooses, or require a specific method?

EPA is proposing to require for the chemical analysis GC/MS, which may be the best method for conducting chemical analyses for these compounds, as all these aryl phosphate base stock components are sufficiently volatile. However, isomers in products such as TCP and TXP are difficult to separate even on capillary columns. Determination of specific components such as TOCP, and analysis of phenolic moieties by gas-liquid chromatography following alkaline hydrolysis of the phosphate esters has been proposed (Ref. 50). Alternatives to GC include:

• Gel permeation chromatography.

• High performance liquid chromatography.

• Supercritical fluid chromatography.

Alternatives to MS (which may be too destructive of the separated particles for good analysis) include:

• Nuclear magnetic resonance.

• Infrared radiation.

• Ion track detector.

Should any of these methods be considered as alternatives, particularly if the proposed method may cause destruction of the sample?

5. Does the exposure information on aryl phosphates support testing for all identified base stocks? Could results of more limited testing be used as a screen to develop whether or not it is necessary to test additional base stocks?

B. Issues Related to Required Testing

1. Should EPA propose another level that would have no production trigger and would include only the hen subchronic neurotoxicity and a one-generation reproductive toxicity test for those chemicals where economic impact is severe?

According to information received by EPA, some of the aryl phosphate base stocks do not have an aggregate production level that EPA has determined will adequately support the required Level 1 testing costs. The tests proposed in Level 1 are based on known toxicity for the category, and, in some instances, on toxicity of certain components of the base stocks.

2. Should EPA require developmental neurotoxicity testing of aryl phosphate base stocks?

EPA is requiring both hen (acute delayed neurotoxicity and NTE, and subchronic delayed neurotoxicity, if triggered) and rat (FOB, MA, NP) neurotoxicity studies, but is not proposing to require developmental neurotoxicity testing at this time. EPA's Science Advisory Panel recommended that one criterion for requiring the developmental neurotoxicity screen be "**** test substances that produce neuropathology in developing or adult animals," and another criterion be "**** strong structure-activity relationships with known neurotoxicants" (Ref. 70). Should EPA propose a developmental neurotoxicity test requirement in a subsequent rulemaking if neurotoxicity test results in the rat are positive?

3. Should EPA again consider investigating whether some form of epidemiological study is indicated?

EPA did not suggest epidemiological neurotoxicity studies in the ANPR because available information suggested that a valid cohort was too difficult to identify. However, the Agency is interested in determining if a valid cohort may now be identified. Epidemiological studies of neurotoxic and/or reproductive effects may be warranted because of the suggestive new toxicity data in these areas.

4. Should EPA require that the rainbow trout ELS test be expanded to include histopathological examination specifically for cataracts, bone development and bone collagen deficits as seen in Ref. 39, or carried for a longer post-hatch period, e.g., 6 months, to better ensure that any such effects will be observed?

EPA is proposing to extend the usual 90 day post-hatch duration of the ELS test in the trout to 120 days post-hatch as a surrogate for a chronic fish test, for which EPA has no guideline. Cataracts and reduced vertebral collagen were seen in long-term studies of at least 3 to 4 months in trout, but not detected in a 30-day study in minnows, although histological precursors were detected (Ref. 39).

5. Should EPA require additional testing for the aryl phosphate base stocks to address memory and other neurobehavioral deficits if brain and blood acetylcholinesterase inhibition is significant?

The proposed subchronic toxicity test would include tests for blood and brain acetylcholinesterase (AChE) inhibition. References cited in the 1971 ACGIH Documentation of the Threshold Limit Values reported significant decreases in plasma cholinesterase in workers exposed to TOCP and of red blood cell cholinesterase in workers exposed to TPP, even though the authors found no other effects (Ref. 4). Of more concern, a recent study on an organophosphate pesticide, diisopropylfluorophosphate, showed significant effects on short- and long-term memory, impaired matching accuracy and lengthened response times at levels at which the only other effect observed was depressed brain AChE (Ref. 11), and only after extended treatment with the chemical.

6. Is there a CBI problem if EPA informs all manufacturers of a given base stock substance that there are other manufacturers of the same substance and who those manufacturers are, and that an aggregate production volume trigger was met for that substance?

7. EPA is aware of the interchangeability of some aryl phosphates for the same end use. To gain a greater understanding of this factor which plays a role in the evaluations of the economic impact of this proposed rule, EPA is requesting the submission of additional data relating to interchangeability.

C. Other Issues

1. Should EPA require reporting of exposure and release information beyond that proposed in the test rule?

EPA is proposing TSCA section 8(a) PAIR reporting for manufacturers of the aryl phosphate base stocks to enable EPA to make better decisions on which base stocks can support the testing. Preliminary information indicates that a great deal of human exposure and

environmental release results from processing and use of products containing aryl phosphate base stocks, suggesting that EPA may miss important information by not requiring processors to report.

2. EPA has defined three production-level triggers, one at 1 million pounds for potential unreasonable risk findings, one at 5 million pounds and one at 10 million pounds for additional testing. EPA solicits comment on whether these triggers comport with manufacturers' ability to pay for the level of testing. Is it appropriate to use these triggers based on a high production/high exposure concern? If an exposure value should be included, what should it be and how could EPA apply it as a triggering mechanism?

V. Economic Analysis of Proposed Rule

EPA has prepared an economic analysis of this proposed rule (Ref. 6). The analysis estimates the costs of conducting the proposed testing for each of the chemicals, including both laboratory and administrative costs, and evaluates the potential for economic impacts as a result of these test costs, using a comparison between a chemical's annualized test costs and its annual revenues.

The estimated total cost of the maximum possible testing for each chemical is $1,076,988 to $1,656,638.

In order to evaluate the potential economic impacts of the proposed testing, test costs are annualized and compared with annual revenues from the chemicals. The annualized test costs, using a 7 percent cost of capital over a period of 15 years are $53,974 to $81,167 for Level 1; for Levels 1 and 2, the costs are $66,681 to $99,516; for all 3 Levels, the costs are $118,247 to $181,890. The costs of chemical analysis were not estimated because no protocols were identified for this test. Therefore these costs may be underestimated.

The comparison between annual costs and revenues suggests that for four chemicals, the maximum test cost may have no significant adverse economic impacts. For the remaining chemicals, the test costs do appear to pose some potential for adverse economic impacts. Please refer to the economic analysis contained in the public record for this rulemaking for more details on test cost estimations and the evaluation of economic impacts. EPA's proposed testing and standards devised to reduce the impact of testing costs is described in Unit III.A of this preamble of this notice.

VI. Availability of Test Facilities and Personnel

EPA has determined that test facilities and personnel are available to perform the testing specified in this proposed rule. (Ref. 8).

VII. Public Meeting

If requests for oral comments are submitted, as indicated in the dates section, EPA will hold a public meeting after the close of the public comment period in Washington, DC. Persons wishing to present comments or attend the meeting should call Mary Louise Hewlett, (202) 260-8162. The meetings are open to the public, but active participation will be limited to those who requested to comment and EPA representatives. Participants are requested to submit copies of their statements by the meeting date. These statements and a transcript of the meeting will become part of EPA's record for rulemaking.

VIII. Comments Containing Confidential Business Information

All comments will be placed in the public file unless they are clearly labeled as Confidential Business Information (CBI) when the comments are submitted.

While a part of the record, CBI comments will be treated in accordance with 40 CFR part 2. A sanitized version of all CBI comments should be submitted to EPA for the public file.

It is the responsibility of the commenter to comply with 40 CFR part 2 in order that all materials claimed as confidential may be properly protected. This includes, but is not limited to, clearly indicating on the face of the comment (as well as on any associated correspondence) that CBI is included, and marking "CONFIDENTIAL", "TSCA CBI" or similar designation on the face of each document or attachment in the comment that contains CBI. Should information be put into the public file because of failure to clearly designate its confidential status on the face of the comment, EPA will presume any such information that has been in the public file for more than 30 days to be in the public domain.

IX. Rulemaking Record

EPA has established a record for this rulemaking, (docket number OPPTS-42038A). This record contains the basic information considered by the Agency in developing this proposal and appropriate **Federal Register** notices.

This record includes the following information:

A. Supporting documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of the chemical category of aryl phosphates to the Priority List (43 FR 16684, April 19, 1978).

(b) Rule requiring TSCA section 8(a) reporting on the chemical category of aryl phosphates (47 FR 26992, June 22, 1982).

(c) Rule requiring TSCA section 8(d) reporting on the chemical category of aryl phosphates (47 FR 38780, September 2, 1982).

(d) TSCA test guidelines cited as proposed test standards for this rule, 40 CFR parts 796, 797, and 798.

(e) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (54 FR 34034, August 17, 1989).

(f) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652, May 17, 1985).

(g) Notice of final rule on data reimbursement policy and procedures (48 FR 31786, July 11, 1983).

(h) Advance notice of proposed rulemaking for aryl phosphates (48 FR 57452, December 29, 1983).

(i) Notice of Inventory Update Rule (51 FR 21447, June 12, 1986).

(j) Notice of Agency's first and second proposed test rules (45 FR 48510, July 18, 1980 and 46 FR 30300, June 5, 1981).

(2) Communications before proposal consisting of:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

B. References

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X. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule would not be major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e., it would not have an annual effect on the economy of at least $100 million, would not cause a major increase in prices, and would not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in this record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 et seq., Pub. L. 96–354, September 19, 1980), EPA is certifying that this test rule, if promulgated, would not have a significant impact on a substantial number of small businesses because: (1) There are only a small number of known small manufacturers, (2) any small processors are not expected to perform testing themselves or to participate in the organization of the testing effort, (3) they will experience only very minor cost in securing exemption from testing requirements, and (4) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and has assigned OMB control number 2070–0033.

Public reporting burden for this collection of information is estimated to average 14,174 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The total public reporting burden is estimated to be 170,088 hours for all.

Send comments regarding the burden estimates for any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070–0033), Washington, DC 20503. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Parts 704 and 799

Chemicals, Chemical fate, Chemical export, Environmental effects, Environmental protection, Hazardous substances, Health, Laboratories, Recordkeeping and reporting requirements, Testing, Incorporation by Reference

Dated: December 26, 1991.

Victor J. Kimm,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Chapter I be amended as follows:

1. In part 704:

PART 704—[AMENDED]

a. The authority citation for Part 704 would continue to read as follows:

Authority: 15 U.S.C. 2607

b. By adding § 704.32 to read as follows:

§ 704.32 Aryl Phosphate Base Stocks.

(a) *Substances for which reporting is required.* The chemical substances for which reporting is required under this rule consist of the category of aryl phosphate base stocks, as defined in § 799.700 of this chapter, that are now listed on, or in the future are added to, the public or confidential portions of the TSCA Inventory of Chemical Substances maintained by EPA under TSCA section 8(b) at any time after the effective date of the final rule. New chemical substances meeting this definition shall also be subject to this section once entered into the TSCA Inventory of Chemical Substances.

(b) *Persons who must report.* The following persons, unless exempt as provided in § 704.5, are subject to the reporting requirements of this rule; a person may be required to report more than once under this section. Those persons who are small manufacturers as defined in § 704.3 are also required to report.

(1) *Initial reporting.* Persons who manufacture or import any substance identified in paragraph (a) of this section for commercial purposes during the person's latest complete corporate fiscal year prior to (the effective date of the final rule) are required to report.

(2) *Subsequent reporting.* Persons who manufacture or import any substance identified in paragraph (a) of this section for commercial purposes after (the effective date of the final rule) are required to report. The persons described in this paragraph (b)(2) include persons who report initially in response to paragraph (b)(1) of this section and persons who commence the manufacture or importation of any substance identified in paragraph (a) of this section after (the effective date of the final rule).

(c) *When to report*—(1) *Initial reporting.* Persons described in paragraph (b)(1) of this section must submit an initial report within 60 days of (the effective date of the final rule).

(2) *Subsequent reporting.* Persons described in paragraph (b)(2) of this section must submit a report within 60 days of the completion of each corporate fiscal year during which they manufacture or import any substance identified in paragraph (a) of this section. Persons shall submit a separate report for each corporate fiscal year in which they are subject to this section.

(3) *Duplicative reporting.* Persons reporting under this section are exempt, pursuant to § 710.35 of this chapter, from duplicative reporting for the Inventory Update Rule.

(d) *What information to report.* All persons subject to this section shall report the following information to EPA:

(1) Company name and headquarters address.

(2) Name, address, and telephone number (including area code) of the company's principal technical contact.

(3) The chemical name and Chemical Abstracts Service Registry Number (CAS number) of each chemical substance identified in paragraph (a) of this section manufactured or imported during the latest complete corporate fiscal year.

(4) The quantity (in pounds) of each such substance manufactured or imported during the latest complete corporate fiscal year.

(5) A cross reference to any letter of intent to test that has been submitted for that substance under 40 CFR 799.700(d).

(e) *Where to send reports.* Reports must be submitted to the U.S. Environmental Protection Agency, TSCA Document Processing Center (TS-790), Rm. L-100, Office of Pollution Prevention and Toxics, 401 M St., SW., Washington, DC 20460, Attn: TSCA section 4, Aryl phosphates.

2. In Part 799:

PART 799—[AMENDED]

a. The authority citation for part 799 would continue to read as follows:

AUTHORITY: 15 U.S.C. 2603, 2611, 2625.

2. By adding § 799.700 to read as follows:

§ 799.700 Aryl phosphate base stocks.

(a) *Scope and purpose.* This section requires persons who manufacture, import, or process a chemical substance in the "aryl phosphate base stocks" chemical category to conduct chemical analysis and testing for health effects, environmental effects, and chemical fate of the substance. The extent of testing for an individual aryl phosphate base stock depends upon its aggregate annual production volume. The testing requirements are divided into two stages. Stage one, which is required of all manufacturers, importers, and processors, involves chemical analysis that will determine the chemical identity of the base stocks produced during the period this rule is in effect. Stage two, which is subdivided into three levels triggered by production volume, involves testing for health and environmental effects, and chemical fate.

(1) *Stage one.* (i) All persons who manufacture, import, or process, or intend to manufacture, import, or process a particular aryl phosphate base stock will be responsible for conducting chemical analysis of that substance pursuant to paragraph (e) of this section.

(ii) From the results of these analyses, EPA will determine whether two or more chemicals are equivalent and whether further tests can be jointly sponsored. For purposes of this section, base stocks with greater than 2 percent variation in a single component (0.1 percent for TOCP) will be considered different base stocks. As provided in paragraph (d)(3) of this section affected persons will be notified of such decisions by certified mail.

(2) *Stage two*—(i) *Level 1.* When the aggregate annual production volume for all manufactures and importers of a particular aryl phosphate base stock is, or reaches, 1 million pounds, all persons who manufacture, import, or process that substance will be responsible for conducting the following testing of the substance pursuant to paragraphs (g)(1)(ii), (h)(2)(i)(B) and (h)(3)(i) of this section: a 120-day post-hatch rainbow trout early life stage (ELS) test, three hen neurotoxicity assays, and a two-generation reproductive effects study.

(ii) *Level 2.* When the aggregate annual production volume for all manufacturers and importers of an aryl phosphate base stock substance is, or reaches, 5 million pounds, all persons who manufacture, import, or process that substance will be responsible for conducting the following testing of the substance pursuant to paragraphs (f)(1), (g)(1)(i) (g)(1)(ii), (h)(1), (h)(2)(i)(B), and (h)(3)(i) of this section: all Level 1 testing plus anaerobic biodegradation, chronic Daphnia, and subchronic toxicity studies.

(iii) *Level 3.* When the aggregate annual production volume for all manufacturers and importers of an aryl phosphate base stock substance is, or reaches, 10 million pounds, all persons who manufacture, import, or process that substance will be responsible for conducting the following testing of the substance pursuant to paragraphs (f), (g), and (h) of this section: all Level 1 and Level 2 testing plus aerobic biodegradation, a microcosm ecosystem test, and developmental toxicity studies, and the subchronic rat neurotoxicity battery.

(b) *Definitions.* In addition to the definitions in section 3 of TSCA and the definitions of § 790.3 of this chapter, the

following definition also applies to this section.

(1) "Aryl phosphate base stocks" are phosphate esters or combination of esters resulting from the reaction of a phenol, mixtures of phenols, or a combination of alkyl-substituted phenols or, in some cases, phenols plus an alcohol, with phosphorus oxychloride ($POCl_3$) or other phosphoric acid derivatives. This definition includes triaryl and mixed aryl/alkyl esters (where one or two of the three ester groups are alkyl).

(2) [Reserved]

(c) *Identification of test substance.* (1) This section applies to any chemical substance within the aryl phosphate base stock category. The chemical substances in this category listed on the TSCA section 8(b) public inventory are identified in this paragraph. Any aryl phosphate base stock substance that meets the category definition in paragraph (b)(1) of this section shall be tested in accordance with this section. Base stocks differing from one another by more than 2 percent in a single component (0.1 percent for TOCP) shall be considered different base stocks for purposes of this rule.

(2) This section also applies to any new chemical substance within the aryl phosphate base stock substance category. Persons subject to this section by virtue of their intention to manufacture or import a new chemical substance in the category of aryl phosphate base stock substances must comply with this section before submitting a premanufacture notification (PMN) under TSCA section 5(a) for such substance.

(3) The following currently manufactured base stock substances meet the category definition and shall be tested:

(i) *tert*-butylphenyl diphenyl phosphate (CAS No. 56803–37–3), or isobutylenated phenol, phosphate (3:1) (CAS No. 68937–40–6) (based on a 1:3 mol ratio isobutylene to phenol).

(ii) bis-(*tert*-butylphenyl) phenyl phosphate (CAS No. 65652–41–7), or isobutylenated phenol, phosphate (3:1) (CAS No. 68937–40–6) (based on a 2:3 mol ratio isobutylene to phenol).

(iii) tris-(*tert*-Butylphenyl) phosphate (CAS No. 78–33–1), or isobutylenated phenol, phosphate (CAS No. 68937–40–6) (based on a 1:1 mol ratio isobutylene to phenol).

(iv) Di-*n*-butyl phenyl phosphate (CAS No. 2528–36–1).

(v) 2-ethylhexyl diphenyl phosphate (CAS No. 1241–94–7).

(vi) Isodecyl diphenyl phosphate (CAS No. 29761–21–5).

(vii) Isopropylphenyl diphenyl phosphate (CAS No. 28108–99–8), or phenol, isopropylated, phosphate (3:1) (CAS No. 68937–41–7) (based on a 1:3 mol ratio propylene to phenol).

(viii) bis-(Isopropylphenyl) phenyl phosphate (CAS No. 28109–00–4), or phenol, isopropylated, phosphate (3:1) (CAS No. 68937–41–7) (based on a 2:3 mol ratio propylene to phenol).

(ix) tris-(Isopropylphenyl) phosphate or phenol, isopropylated, phosphate (3:1) (CAS No. 68937–41–7) (based on a 1:1 mol ratio propylene to phenol).

(x) Tricresyl phosphate (CAS No. 1330–78–5), or tar acids, cresylic, phenyl phosphate (CAS No. 68952–35–2)

(xi) Triphenyl phosphate (CAS No. 115–86–6).

(xii) Trixylyl phosphate (CAS No. 25155–23–1), or tar acids, cresylic, C–8 rich, phenyl phosphate (CAS No. 68952–33–6).

(d) *Persons required to submit study plans, conduct tests, submit data, and the EPA notification plan*—(1) *Chemical analysis.* All persons who manufacture (including persons who import) or process or intend to manufacture or process any aryl phosphate base stock substance that meets the definition in paragraph (b)(1) of this section including, but not limited to, those listed in paragraph (c)(3) of this section, from the effective date of this section to the end of the reimbursement period, are subject to chemical analysis testing and shall submit letters of intent to test, submit study plans, conduct tests and submit data as described in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking.

(2) *Chemical fate, environmental effects and health effects tests.* All persons who manufacture, import or process, or intend to manufacture, import or process any aryl phosphate base stock substance that meets the definition in paragraph (b) of this section, from the effective date of this section to the end of the reimbursement period, shall submit letters of intent to test, submit study plans, conduct tests and submit data as described in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rule-making.

(e) *Chemical analysis*—(1) *Required testing.* GC/MS analysis shall be performed on every aryl phosphate base stock substance. The provisions of § 792.105(a) of this chapter require that for each study done under Good Laboratory Practice Standards, the identity, strength, purity and composition stability shall be determined for each batch and shall be documented before the initiation of the study. Any individual aryl phosphate positional isomer, except tri-ortho-cresyl phosphate (TOCP), or any other substance present in a base stock, must be identified and quantitated if present at a concentration of 1 percent or greater; quantitation is required to ±0.5 percent. TOCP shall be quantitated, at ±0.05 percent, unless present at less than 0.10 percent.

(2) *Reporting requirements.* Chemical analysis shall be completed and the final report submitted to EPA no later than 6 months after the effective date of this test rule or, for new chemicals, with the Premanufacture Notification under TSCA section 5(a).

(3) *EPA notification of manufacturers.* The Agency will notify manufacturers by certified mail if their chemical is equivalent to another manufacturer's and costs may be shared, or if they are required to begin additional testing under this test rule without co-sponsors. The notification will also include for each manufacturer the level of testing that should begin for the specific aryl phosphate base stock substance and will specify which of any equivalent substances must be tested.

(f) *Chemical fate*—(1) *Required testing*—(i) Anaerobic biodegradation testing shall be performed in accordance with § 796.3140 of this chapter upon receipt of EPA's written notification to manufacturers, pursuant to paragraph (e)(3) of this section, of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 5 million pounds.

(ii) Aerobic biodegradation testing shall be conducted using clean freshwater sediments in accordance with the method described in an article by Bourquin (1977) entitled "An Artificial Microbial Ecosystem for Determining Effects and Fate of Toxicants in a Salt-Marsh Environment", published in *Developments in Industrial Microbiology*, vol. 18, Chapter 11, 1977, which is incorporated by reference. A copy of this material incorporated by reference is available in the TSCA Public Reading Room, Rm. NE–G004, 401 M St., SW., Washington, DC 20460. This material is also available for inspection at the Office of the Federal Register, Rm. 8401, 1100 L St., NW., Washington, DC 20408. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This method is incorporated as it exists on the effective date of this section and notice of any change to the method will

be published in the **Federal Register**. The aerobic biodegradation test is required upon receipt of EPA's written notification to manufacturers, pursuant to paragraph (e)(3) of this section, of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 10 million pounds.

(2) *Reporting requirements.* (i) Each chemical fate test shall be completed and the final report submitted to EPA within 12 months after receipt of EPA's written notification that the anaerobic biodegradation or the aerobic biodegradation testing must be initiated.

(ii) Progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after receipt of EPA's written notification that testing must be initiated until submission of the final report.

(g) *Environmental effects*—(1) *Required testing*—(i) *Daphnid chronic toxicity test.* The chronic test for Daphnia shall be performed according to § 797.1350 of this chapter upon receipt of EPA's written notification to manufacturers, pursuant to paragraph (e)(3) of this section,of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 5 million pounds.

(ii) *Fish ELS toxicity test.* (A) The ELS test for aquatic toxicity in the rainbow trout shall be performed according to § 797.1600 of this chapter, except the provisions of paragraph of § 797.1600(c)(1)(i), upon receipt of EPA's written notification to manufacturers, pursuant to paragraph (e)(3) of this section, of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 1 million pounds.

(B) For the purpose of this section, the following provisions also apply:

(*1*) The test terminates following 120 days of post-hatch exposure (for an approximate total exposure period of 150 days).

(*2*) [Reserved]

(iii) *Generic freshwater microcosm test.* The generic freshwater microcosm test shall be performed according to proposed § 797.3050 (52 FR 36344, September 28, 1987) upon receipt of EPA's written notification to manufacturers, pursuant to paragraph (e)(3) of this section, of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 10 million pounds.

(2) *Reporting requirements.* (i) The Daphnid chronic toxicity test shall be completed and the final report submitted to EPA within 12 months after receipt of EPA's written notification that testing must be initiated.

(ii) The fish ELS test in the rainbow trout shall be completed and the final report submitted to EPA 18 months after receipt of EPA's written notification that testing must be initiated.

(iii) The generic freshwater microcosm test shall be completed and the final report submitted to EPA 24 months after receipt of EPA's written notification that testing must be initiated.

(iv) Progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after receipt of EPA's written notification that testing must be initiated until submission of the final report

(h) *Health effects*—(1) *Subchronic toxicity*—(i) *Required testing.* (A) Oral toxicity testing in the Sprague-Dawley rat shall be performed by gavage in accordance with § 798.2650 of this chapter, except the provisions of § 798.2650(e)(9)(i)(B), upon receipt of EPA's written notification to manufacturers, pursuant to paragraph (e)(3) of this section, of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 5 million pounds.

(B) For the purpose of this section, the following provisions also apply:

(*1*) Blood acetylcholinesterase activity shall be determined pre-dosing, and blood and brain acetylcholinesterase activity at termination.

(*2*) [Reserved]

(ii) *Reporting requirements*—(A) Subchronic toxicity testing shall be completed and a final report submitted to EPA within 18 months after receipt of EPA's written notification that testing must be initiated.

(B) Progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after receipt of EPA's written notification that testing must be initiated until submission of the final report.

(2) *Neurotoxicity*—(i) *Required testing.* (A) Gavage neurotoxicity testing in the Sprague-Dawley rat shall be performed according to § § 798.6050, 798.6200 and 798.6400 of this chapter upon receipt of EPA's written notification to manufacturers of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 10 million pounds (see paragraph (e)(3) of this section). Tests conducted according to § 798.6050 and § 798.6200 of this chapter shall be both acute and subchronic. The test conducted according to § 798.6400 of this chapter shall be subchronic. The acute studies according to § 798.6050 and § 798.6200 of this chapter may be incorporated into the subchronic neurotoxicity tests. The subchronic neurotoxicity tests may be combined with the testing required by paragraph (h)(1)(i) of this section if the test protocol allows. The cited guidelines provide standard information for these procedures.

(B) Gavage neurotoxicity testing in the hen shall be performed according to § § 798.6450, 798.6540, and 798.6560 of this chapter upon receipt of EPA's written notification to manufacturers of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 1 million pounds (see paragraph (e)(3) of this section). Testing according to § 798.6450 of this chapter shall be performed in conjunction with § 798.6540 of this chapter. However, if results for a substance tested according to § 798.6540 and § 798.6450 of this chapter are negative, then testing according to § 798.6560 of this chapter need not be conducted on that substance.

(ii) *Reporting requirements*—(A) Rat neurotoxicity studies shall be completed and the final reports submitted to EPA within 18 months after receipt of EPA's written notification that testing must be initiated until submission of the final report.

(B) The hen neurotoxicity studies pursuant to § 798.6450 and § 798.6540 of this chapter shall be completed and final reports submitted to EPA within 6 months after receipt of EPA's written notification that testing must be initiated. If the subchronic study, § 798.6560 of this chapter as specified in paragraph (g)(2)(i)(B) of this section, is necessary, the final reporting date will be 18 months after receipt of EPA's written notification that testing must be initiated.

(iii) Progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after receipt of EPA's written notification that testing must be initiated until submission of the final report.

(3) *Reproduction and fertility*—(i) *Required testing.* (A) Reproduction and fertility testing shall be performed by gavage in the Sprague-Dawley rat according to § 798.4700 of this chapter, except the provisions of paragraphs (c)(7)(i), (c)(8)(ii), (c)(9)(i) and (c)(9)(iii) of § 798.4700, upon receipt of EPA's written notification to manufacturers,

pursuant to paragraph (e)(3) of this section, of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 1 million pounds.

(B) For the purposes of this rule, the following provisions apply:

(*1*) Data on female cyclicity in P and F_1 females over the last 3 weeks prior to mating shall be described. The method of Sadleir (1979), found under paragraph (i)(6) of this section, or an equivalent method may be used. Data shall be provided on whether the animal is cycling and the cycle length. P and F_1 females shall continue to be exposed to the test substance through the 3 weeks prior to mating. The ovary shall be serially sectioned with a sufficient number of sections examined to adequately detail oocyte and follicular morphology. The methods of Mattison and Thorgierson (1979) found under paragraph (i)(3) of this section and Pederson and Peters (1988) found under paragraph (i)(4) of this section or their equivalent provide guidance. The strategy for sectioning and evaluation is left to the discretion of the investigator, but shall be described in detail in the test protocol and final report.

(*2*) Measurements of homogenization-resistant spermatid count, caudal epididymal sperm density and motility will be provided. Assessments of motility include quantification of progressively motile and immotile sperm, and techniques that utilize video recording of the samples, as well as objective measurement of the motility parameters. Guidance for assessing motility is provided by Linder et al. (1986) found under paragraph (i)(2) of this section, and Klinefelter et al. (1991) found under paragraph (i)(1) of this section, or their equivalent.

(*3*) Weights of the testes, epididymes (total and cauda), pituitary, seminal vesicles (with coagulating glands), prostate, ovary and uterus shall be recorded at the time of sacrifice of the P and F_1 animals. Histopathology of the testes shall be conducted on the P and F_1 males at the time of sacrifice. Particular attention shall be directed toward achieving satisfactory quality from fixation and embedding, and preparations shall follow the recommendations of Russell et al. (1990) found under paragraph (i)(5) of this section, or an equivalent. Histologic analyses shall include evaluations of the spermatogenic cycle, i.e., the presence and integrity of the 14 cell stages. These evaluations follow the guidance provided by Russell et al. (1990) found under paragraph (i)(5) of this section, or an equivalent.

(ii) *Reporting requirements*—(A) The reproductive and fertility studies shall be completed and final reports received by the EPA 24 months after receipt of EPA's written notification that testing must be initiated.

(B) Progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after receipt of EPA's written notification that testing must be initiated until submission of the final report.

(4) *Developmental toxicity*—(i) *Required testing.* Developmental toxicity studies shall be performed by gavage in the rat and rabbit according to § 798.4900 of this chapter upon receipt of EPA's written notification to manufacturers, pursuant to paragraph (e)(3) of this section, of a particular aryl phosphate base stock substance that EPA has determined that the aggregate annual production volume of that substance equals or exceeds 10 million pounds.

(ii) *Reporting requirements*—(A) The developmental toxicity studies shall be completed and final reports submitted to EPA within 12 months after receipt of EPA's written notification that testing must be initiated.

(B) Progress reports shall be submitted to EPA at 6-month intervals, beginning 6 months after receipt of EPA's written notification that testing must be initiated until submission of the final report.

(i) *References.* For additional background information, the following references should be consulted.

(1) Klinefelter, G.R., Gray, L.E., Jr. and J.D. Suarez. "The method of sperm collection significantly influences sperm motion parameters following ethane dimethanesulfonate administration in the rat." *Reproductive Toxicology.* 5:39–45 (1991).

(2) Linder, R.E., Strader, L.F. and W.K. McElroy. "Measurement of epididymes sperm motility as a test variable in the rat." *Bulletin of Environmental Contaminant Toxicology.* 36:317–324 (1986).

(3) Mattison, D.R. and Thorgeirsson, S.S. "Ovarian aryl hydrocarbon hydroxylase activity and primordial oocyte toxicity of polycyclic aromatic hydrocarbons in mice." *Cancer Research.* 39:3471–3475 (1979).

(4) Pederson, T. and Peters, H. "Proposal for classification of oocytes and follicles in the mouse ovary." *Journal of Reproduction and Fertility.* 17:555–557 (1968).

(5) Russell, L.D., R.A. Ettlin, Sinha Hikim, A.P. and E.D. Clegg. "Histological and histopathologic evaluation of the testis." Cache River Press: Clearwater, FL (1990).

(6) Sadleir, R.M.F.S. "Cycles and seasons." In: *Reproduction in Mammals: I. Germ Cells and Fertilization.* Austin, C.R. and R.V. Short, eds. Cambridge Press: New York, NY (1979).

(j) *Effective date.* (1) The effective date of the final rule will be (insert date 44 days after date of publication of final rule in the **Federal Register**).

(2) The guidelines cited in this section are referenced here as they exist on (insert effective date of the final rule).

(Information collection requirements have been approved by the Office of Management and Budget under control number 2070–0033.)

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